In the Matter Of:

K.C., ET AL

-v-

INDIVIDUAL MEMBERS OF MEDICAL LICENSING BOARD OF INDIANA, ET AL

Elaine Cox, M.D.

May 31, 2023

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., et al.,	)	
	)	
Plaintiffs,	)	
	)	
-v-	)	CASE NO.
	)	1:23-cv-00595-JPH-KMB
THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, et al.,	)	
	)	
Defendants.	)	

The 30(b)(6) deposition upon oral examination of RILEY CHILDREN'S HEALTH by ELAINE COX, M.D., a witness produced and remotely sworn before me, Debbi S. Austin, RMR, CRR, Notary Public in and for the County of Hendricks, State of Indiana, taken on behalf of the Defendants via Zoom videoconference on May 31, 2023, at 9:01 a.m., pursuant to the Federal Rules of Civil Procedure.

STEWART RICHARDSON & ASSOCIATES
Registered Professional Reporters
(800)869-0873

APPEARANCES

(All participants via Zoom videoconference)

FOR THE PLAINTIFFS:

Kenneth J. Falk, Esq.
Gavin M. Rose, Esq.
Stevie Pactor, Esq.
ACLU OF INDIANA
1031 East Washington Street
Indianapolis, IN 46202
kfalk@aclu-in.org
grose@aclu-in.org
spactor@aclu-in.org

Chase Strangio, Esq.
AMERICAN CIVIL LIBERTIES
UNION FOUNDATION
125 Broad Street
New York, NY 10041
cstrangio@aclu.org

FOR THE DEFENDANTS:

Thomas M. Fisher, Esq.
OFFICE OF THE ATTORNEY GENERAL
302 West Washington Street
IGCS Fifth Floor
Indianapolis, IN 46204
tom.fisher@atg.in.gov

FOR THE DEPONENT AND INDIANA UNIVERSITY HEALTH:

Joshua J. Minkler, Esq.
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204
josh.minkler@btlaw.com

APPEARANCES (CONT'D.)

ALSO PRESENT: Alli Emhardt, Assistant General Counsel
Indiana University Health

Joannie Geuder
Mylene Laughlin
Andrew Shaw
Brandon Splitter
Bailey Steinhauer
Shay Storz
John Vastag
Roarke Matchett

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Fertility Preservation for Transgender and Gender-Nonbinary People

Riley Children's Gender Health Team

Why should transgender and gender-nonbinary people think about fertility preservation?

It is important to talk about fertility preservation (saving eggs or sperm to use in the future) before you make decisions about gender-affirming medical care. If you use hormones like estrogen or testosterone (gender-affirming hormone therapy) or have surgery to remove your testes or ovaries (gonadectomy), it can change your fertility. Fertility is the ability to create a baby with your egg or sperm.

Researchers have talked to transgender and nonbinary adults about creating families. Some transgender and nonbinary adults feel like they missed out on the chance to have children who are genetically related to them. Some of them would rather become parents by adopting. Many of them think we should discuss the different choices you have before you start medical treatments that could change your fertility.

You may not want to be a parent, or maybe right now it's hard to imagine being a parent. Your thoughts about this may change as you get older. It is important for you to know what can be done now and in the future.

Here are some things related to fertility preservation that you might want to talk about with us:

- ***Future desire to be a parent***. Before starting hormones, think about whether you want the option to have children who are genetically related to you in the future. Hormones and surgeries can decrease your fertility or cause you to become infertile. It is important to make decisions about fertility preservation now before you start those treatments.
- ***Understanding the process***. It's important to understand the options for fertility preservation that are available. It's also important to understand what your future reproductive options are. You may want to know about the success rates of procedures that use saved eggs/sperm/embryos.
- ***Cost.*** The costs of fertility preservation are not covered by most insurance plans. One cost is the retrieval and storage of eggs/sperm/embryos. Another cost is for future procedures, such as IVF (in vitro fertilization). IVF is a procedure where doctors help make an embryo (the first stage of fertilization) by mixing your unfrozen eggs or sperm with another person's eggs or sperm. The embryo can then be put into a uterus—either yours, if you have one, or another person's. This can also be done with unfrozen embryos.

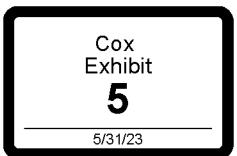
Parents/guardians are also very important when it comes to helping their child think about their options for fertility preservation. They usually have to give consent for any procedures. They also need to consider any effects on their child's mental and physical health. Our team members are available to discuss these issues or other concerns.

For people who have not started puberty:

You do not have to start puberty in order to do fertility preservation. You can have tissue from your ovaries or testes stored before you start or finish puberty. Doctors use anesthesia (giving you medicine so you don't feel pain) to do a small surgery to remove a piece of tissue from your ovaries or testes to save it. Right now, this is the only fertility preservation option for people who have not started puberty yet or who are in the earlier stages of puberty. It is considered experimental.

For people who have started puberty and are using (or thinking about using) puberty blockers:

If you are already on puberty blockers and want to do fertility preservation before you start hormone therapy, you can save eggs or sperm to use in the future. However, most people will need to stop the



puberty blocker and let their body to go through puberty for a while before their sperm or eggs can be collected. Sometimes adolescents can save tissue from their testes or ovaries for future use.

For people who have finished puberty and started hormones (or plan to start hormones or have surgery in the future):

If you have started gender-affirming hormones but still have your testes or ovaries, you usually need to stop taking your hormones for a while so that your fertility comes back. Then you can do fertility preservation. It may take 3-6 months for your fertility to come back after you stop the hormones. However, some people have permanent fertility loss after starting hormones. Some people will need to try one of the procedures that we talk about below. Once your testes or ovaries are removed, fertility preservation isn't an option anymore. It is important to think about fertility choices before you have that surgery.

If you were born with ovaries:

- **Retrieving and freezing ovarian tissue (ovarian tissue cryopreservation).** This is currently experimental. It has been performed successfully at centers with experts in this area. A doctor would take a piece of tissue from your ovaries and freeze it. Later on, the ovary tissue is unfrozen and matured in a laboratory to make eggs. Then doctors use those eggs to make an embryo that is put back into a uterus to make a pregnancy. Another option is that the unfrozen tissue could be put back into your body to let your body try to make eggs on its own.
- **Retrieving and freezing eggs (oocyte cryopreservation**). A doctor would remove the eggs from your body and then freeze them. Later on, the eggs can be unfrozen and fertilized with sperm from a donor or a partner to make an embryo. Then embryos can be put into a uterus to make a pregnancy. The uterus can belong to a surrogate (someone who is okay with carrying your embryo for you in their body until the baby is born), your partner (if they can experience pregnancy), or you (if you have not had surgery to remove your uterus and would like to experience the pregnancy yourself). If you are taking testosterone, you will have to stop taking the testosterone before the doctor removes your eggs (or before embryos are put into your uterus if you want to be pregnant).
- **Retrieving eggs to create embryos with sperm from a donor or partner (embryo cryopreservation).** If an embryo was made it can be frozen and then unfrozen later. Then the embryo can be carried by a surrogate or by you or your partner (if one of you has a uterus and wants to be pregnant). Remember that if you are taking testosterone, you will have to stop taking it before the doctor removes your eggs to make the embryo (or before embryos are put into your uterus if you want to be pregnant).

If you were born with testicles:

- **Retrieving and freezing sperm.** Sperm are removed from your body by masturbating, by vibration or electrical stimulation, or by surgery. Then the sperm are saved by freezing. Later on, the sperm can be unfrozen and fertilized with an egg (from a donor or your partner) to make an embryo. Then doctors can put the embryo inside your partner (if they can experience pregnancy) or a surrogate (someone who is okay with carrying your embryo for you in their body until the baby can be delivered). If you decide to remove the sperm from your body by masturbating, you can do this with an at-home kit, or you can do it in a doctor's office.
- **Testicular tissue preservation**. This is experimental. Doctors remove a small piece of your testicle tissue and send it to a center where it will be stored for you to use in the future.

You don't have to use your sperm or eggs to become a parent. You can adopt, be a foster parent, or have someone else carry the pregnancy with donated sperm, eggs, or embryos. You can also choose not to be a parent. We want everyone to know what their options are so that they can make the best decision about their own future.

Hormone therapy: Testosterone

What is the goal of testosterone therapy?

- Testosterone has two main jobs: 1) it causes masculinizing changes to occur throughout the body, and 2) it suppresses the production of estrogen. Some of the changes caused by testosterone are permanent (they would remain if testosterone was stopped), and other changes are reversible.

How is testosterone administered?

- Testosterone is available as injections, cream or gel. Injections are administered either every 2 weeks intramuscularly (into the muscle) or every week subcutaneously (under the skin). Nursing staff provides injection training here at clinic. Cream and gels are absorbed through the skin and are applied daily.

What are the irreversible effects of testosterone?

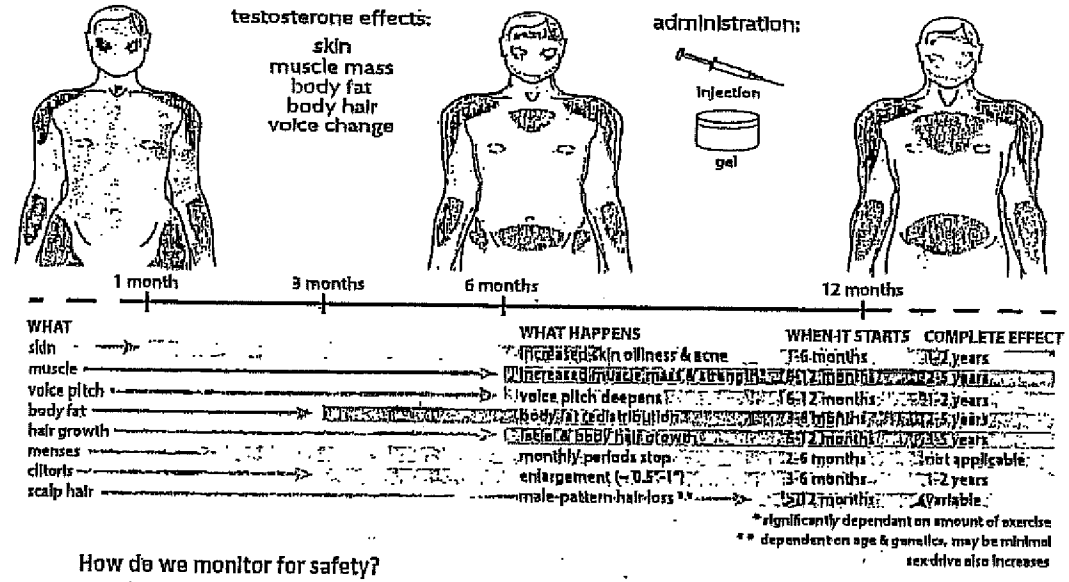
- Testosterone causes voice deepening, clitoral growth, body/facial hair growth, and sometimes male-pattern balding (also influenced by age, genetics). Testosterone may irreversibly affect fertility. Desires for fertility should be considered prior to starting hormones, and for those seeking fertility preservation (or education about fertility preservation), referrals can be made to Lurie's fertility preservation team.

What are some of the reversible effects of testosterone?

- Testosterone causes increased muscle tone, fat redistribution (hips → stomach area), skin oiliness and acne. Mood changes (often irritability, having a "shorter fuse") and heightened sex drive may occur. Menstrual cycles will change and eventually stop after some time. There may be genital changes caused by low estrogen levels.

What are some of the known side effects and risks of testosterone?

- Testosterone may increase your metabolic risk profile – that is, the risk for conditions such as heart disease, diabetes, high cholesterol or blood pressure. The risk for heart disease is higher for people who smoke cigarettes, are overweight or have a family history of heart disease.
- Testosterone causes hematocrit, the proportion of red blood cells in a volume of blood, to increase. This blood thickening, at high levels, can be life-threatening, causing stroke or a heart attack.
- Testosterone can also cause increased appetite, headaches and acne.



How do we monitor for safety?

- Labs (bloodwork) are collected prior to starting hormones and every 3 months for the first year of treatment. In the second year labs are checked every 6 months. Tests that are monitored include cholesterol, liver tests, hematocrit and hormone levels. These labs can be drawn at Lurie's or at a local facility.

How quickly will changes develop?

- Remember, it's normal to want to see changes occur rapidly, but (just like in puberty) these changes take time! Most changes start to begin ~3-6 months after starting testosterone and take years to fully develop.

Will I look like my friend ____??

- Remember, everyone experiences puberty differently. Factors other than testosterone (such as genes!) affect appearance. It's impossible to predict exactly what changes will develop.
- It's important to take the prescribed dose of testosterone. Taking more increases health risks.
- Always tell your health care provider if you have questions or concerns about your health.

Cox Exhibit 6 5/31/23

IUH00003893

ORAL CONTRACEPTION CONSENT

Place your initials before each statement to indicate that you have read, understand, and agree with the statement.

____ I have been given information on other forms of birth control and I have had all of my questions answered. I have voluntarily chosen the birth control pill as my method of birth control, if I need birth control.

____ I have been informed that I must take the birth control pills correctly in order to prevent pregnancy. The typical effectiveness of the pill is 97-98% protective, but skipping or missing pills puts me at risk for pregnancy.

____ I understand that birth control pills will not prevent infection. I need to have my partner use condoms to prevent possible infection with sexually transmitted diseases, including HIV.

____ Missing pills, and vomiting and/or diarrhea may decrease the pill's effectiveness. I understand that I should use a backup method of birth control (condoms) as discussed with my provider in these instances to decrease my risk of pregnancy.

____ I understand that it is important to discuss all other medications that I am taking as some prescriptions may interfere with the pill's effectiveness.

____ I understand it is common to experience breast tenderness, nausea, dizziness, and spotting during the first three months of pills use. By taking my pills every day at approximately the same time and with food, I may decrease some of these symptoms.

____ I understand that besides preventing pregnancy, the pills also have some health benefits as decreasing blood flow and menstrual cramps and helping to regulate my period. In addition, the use of pills may also improve acne.

____ I understand that by taking birth control pills, there is also a chance of decreased risk for ovarian cysts, ovarian and endometrial cancer, pelvic inflammatory disease, anemia, premenstrual syndrome, and mid-cycle pain.

____ I have been informed of the **possible side effects** of birth control pills:

- Nausea
- Headaches
- Spotting between periods
- Breast tenderness
- Mood changes-depression
- Weight gain or weight loss
- Worsening of acne

____ I understand that birth control pills may also be associated with **minimal risk** for:

- Increased cholesterol – but Usually HDL – the "good cholesterol"
- Increase in blood pressure
- Blood clots of the lungs or legs
- Gall bladder disease

____ I understand that **serious pill-related health problems** are rare, but may occur. Therefore, I agree that if I have any of the following danger signs, I will call the clinic, contact my health care provider, or go to the nearest emergency department or immediate care center:

- Severe abdominal pain
- Severe headache
- Severe leg pain
- Chest pain
- Visual changes
- One-sided body weakness and/or numbness
- Yellowing of the skin/eyes

____ I understand that the potential risk to life and health is greater from pregnancy than from pill use.

____ I have had the opportunity to read the Birth Control fact sheet, discuss the risks and benefits of taking "the pill", and review any questions or concerns I have with my health care provider.

____ I understand the importance of returning to the clinic for routine follow-up health care or at any time I am experiencing a problem. I am aware of the need for a yearly physical exam or check-up.

Patient's signature _____ / Date

Staff Signature _____ / Date

INDIANA UNIVERSITY
DEPARTMENT OF PEDIATRICS
School of Medicine

DEPO-PROVERA CONSENT

Place your initials before each statement to indicate that you have read, understand, and agree with the statement.

____ I am aware that there are many birth control methods to choose from. I have been told about the benefits, disadvantages, and known risks of using Depo-Provera.

____ I am aware that the typical effectiveness of Depo is 97-99.7%.

____ I understand that if I have the following health problems I should seek immediate care at the clinic or the emergency department:

- Sharp chest pain
- Coughing up blood or sudden shortness of breath
- Sudden severe headache or vomiting
- Dizziness or fainting
- Problems with my eyesight or speech
- Weakness or numbness in an arm or leg
- Severe pain or swelling in the lower leg
- Severe pain or tenderness in the lower abdominal area
- Heavy vaginal bleeding (1-2 pads every 1-2 hours for a few hours)
- Persistent pain, pus, or bleeding at the injection site

____ I understand that when I stop using Depo-Provera, it could take several months before my regular menstrual cycle resumes. Taking birth control pills or using the contraceptive patch for 3 months may help to regulate my periods more quickly.

____ I understand that it could take from a few weeks to as long as months after my last injection in order to become pregnant. If I DO NOT desire pregnancy, I must use another method of birth control immediately after stopping the Depo.

____ I understand that the following are the MOST COMMON side effects of Depo-Provera

- An increase in appetite that may lead to weight gain
- Irregular menstrual bleeding or spotting
- Menstrual like cramps
- Amenorrhea (no periods)

____ I understand that the following are the LEAST COMMON side effects of Depo-Provera and occur less frequently:

- Headaches
- Bloating
- Moodiness or Depression
- Acne
- Swelling of the hands or feet
- No hair growth or excessive hair loss
- Nausea
- Breast swelling and/or tenderness
- Nervousness
- Dizziness

____ I understand the BLACK BOX WARNING associated with Depo-Provera:

- Women who use Depo-Provera may lose significant bone mineral density. Bone loss is greater with increasing duration of use (e.g. longer than 2 years) and may not be completely reversible.
- It is unknown if use of Depo-Provera during adolescence or early adulthood will reduce peak bone mass and increase risk for osteoporotic fracture in later life.
- Depo-Provera should be used as a long-term birth control method only if other methods are inadequate

____ I understand the Depo-Provera does not protect me from the AIDS virus or other sexually transmitted infections. I need to use condoms for this protection.

____ I understand that I need to return every 11-13 weeks for another injection in order for this method to continue working. I am aware that I need to return for an annual physical exam.

____ I have had the opportunity to read the Depo-Provera Fact Sheet, review it with my nurse and have any questions I may have answered. I know I may call my nurse for future questions or concerns and if I am experiencing any side effects. I understand the importance of rescheduling a missed appointment as soon as possible.

Patient's Signature Date

Staff Signature Date

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CH-898 (MAY 16)
Page 1 of 1

Indiana University Health

CONSENT FOR INTRAUTERINE DEVICE PLACEMENT

Patient Sticker

By signing this form, I agree to the procedure(s) listed here. _____

Intrauterine Device Placement

☐ ParaGuard Intrauterine Device ☐ Mirena Intrauterine System

☐ Liletta

to be done by _____, members of Indiana University Health medical or other licensed personnel staff.

From this point on

- all procedures will be called the "procedure"; and
- the persons performing the procedure will be called "treating practitioner."

The exceptions to my consent are as follows:

_____

_____

I understand and agree to the following items.

- Residents and students may help with my care.
- Medical staff other than the treating practitioner may do part of my procedure.
- Industry representatives may be in the room to consult during my procedure.
- The treating practitioner may do other procedures not listed here if they are needed.
- A bad outcome may occur. A bad outcome does not mean care was not appropriate.
- The anesthesiologist or treating practitioner will give me an anesthetic. I have been told about the risks of anesthesia. These include death, injury to my teeth, throat and mouth, other injury and damage to my dentures.
- I agree to get blood and/or blood products any time during this hospital stay if the treating practitioner thinks I need it. I have been told about the risk of getting blood. I have been told if there are other choices. If I need blood or blood products, I agree to the risks that include allergic reactions, infections (hepatitis and AIDS), intravascular fluid overload, and chemical imbalances.
- Parts of my body taken out during surgery can be thrown away or used for research so long as my name is not used.
- Pictures may be taken and used for teaching as long as my name is not used.
- I have talked with the treating practitioner about the procedure, why I need it, the expected outcome, the risks, the chances of success, risks, benefits and results of other treatments, and what could happen if I do not have the procedure.
- I have been told about other choices, including not having the procedure, other procedures, medicine, and therapy.
  - Other choices: _____
- I have been told about the risk of the procedure, which include but are not limited to bleeding, infection, injury, scarring, damage to parts of my body, and death. Other risks: _____

RISKS: Unplanned pregnancy (chance of pregnancy is less than one in one hundred). Ectopic pregnancy (pregnancy in the tubes). If a pregnancy occurs with an IUD in place, it may result in miscarriage. Pelvic infection (may cause infertility, serious infection, need for surgery or even hysterectomy). Perforation (hole) in the uterus during placement of IUD (may require surgery to remove IUD). Expulsion of the IUD. I will have changes in my period while using the IUD.

_____
Signature of Patient / Surrogate

_____
Time Signed Date Signed

_____
If Signed by Surrogate, Relationship to Patient

OPTIONAL:

Additional Adult Witness Signature

Time Signed Date Signed

TREATING PRACTITIONER USE ONLY

I have discussed with the patient the nature of the proposed care, treatment, services, medications, interventions or procedures; the potential benefits, risks or side effects, including potential problems related to recuperation; the likelihood of achieving care, treatment and service goals; the reasonable alternatives to the proposed care, treatment and service; the relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services; and when indicated, any limitations on the confidentiality of information learned from or about the patient.

Signed: _____ Date: _____ Time: _____

DOCUMENTATION OF EMERGENT/URGENT PROCEDURE

This procedure was performed emergently.

Signed: Date: Time:

NEXPLANON® (etonogestrel implant)
Radiopaque
Subdermal Use Only

PATIENT CONSENT FORM

I understand that there are many birth control methods and that each has its own benefits, risks and potential side effects. The insertion of NEXPLANON requires a surgical procedure performed by a healthcare provider who is trained on the use of this product. Like all surgical procedures, the outcomes are best with healthcare providers who are experienced.

By completing this Patient Consent Form, I am consenting to the insertion of NEXPLANON and acknowledging that I have read and understand the following points and made an informed and careful decision to use NEXPLANON.

- NEXPLANON is an implant that releases a hormone (etonogestrel) to prevent pregnancy. It is inserted during a surgical procedure and it can be used for up to three years.
- NEXPLANON helps to keep me from getting pregnant but does not protect me against HIV infection (the virus that causes AIDS) or other sexually transmitted diseases.
- No contraceptive method is 100% effective, including NEXPLANON.
- It is important to have the NEXPLANON implant placed in my arm at the right time of my menstrual cycle in order to prevent pregnancy.
- NEXPLANON is placed just under my skin on the inside of my upper arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- NEXPLANON should not be deeply inserted. An implant that is inserted deeply may have been placed in muscle tissue or, in rare instances, a blood vessel. A deep insertion may cause the implant to move beyond the implant site.
- After NEXPLANON is placed in my arm, both my healthcare provider and I should check that it is in place by gently pressing my fingertips over the skin where the implant was placed. I should be able to feel both ends of the implant. If I cannot feel the implant, it may not have been inserted or it may have been inserted deeply. In this case, I need to use a non-hormonal birth control method (such as condoms or barrier methods) until my healthcare provider confirms the implant is in place. I may need special tests to check that the implant is in place. Once my healthcare provider has located the implant, it should be removed.
- Incomplete insertions or infections may cause NEXPLANON to come partially or entirely out of my arm.
- Most women have changes in their menstrual bleeding patterns while using NEXPLANON. I also will likely have changes in my menstrual bleeding pattern while using NEXPLANON. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should contact my healthcare provider as soon as possible.
- NEXPLANON must be removed at the end of three years, but it can be removed earlier if I want. I may become pregnant as early as the first week after removal of the implant.
- Removal is usually a minor procedure. If NEXPLANON was inserted deeply, the removal may be more difficult or, in rare cases, impossible. Special procedures, including imaging methods to locate the implant and surgery in the hospital, may be needed. Difficult removals may cause pain and scarring and may result in injury to nerves and blood vessels. If the implant is not removed, its effects will likely continue.
- I have read and understand all of the information in the Patient Labeling for NEXPLANON, including the risks of using NEXPLANON, possible side effects, and warning signs of medical problems. Any questions I have about the information in the Patient Labeling and about using NEXPLANON have been answered by my healthcare provider.
- I should tell all my healthcare providers that I am using NEXPLANON.
- I need to have a medical checkup regularly and at any time I am having problems.
- For additional information and full prescribing information, please call toll free 1-844-674-3200 or log on to www.nexplanon.com.

35258
CH-1096 (JAN 12)
Effective 2012

Indiana University Health

CONSENT FOR PROCEDURE

By signing this form, I agree to the procedure(s) listed here. _____

_____

_____

_____

to be done by _____, _____

members of Indiana University Health medical or other licensed personnel staff.

From this point on

- all procedures will be called the "procedure"; and
- the persons performing the procedure will be called "treating practitioner".

The exceptions to my consent are as follows:

_____

_____

I understand and agree to the following items.

- Residents and students may help with my care.
- Medical staff other than the treating practitioner may do part of my procedure.
- Industry representatives may be in the room to consult during my procedure.
- The treating practitioner may do other procedures not listed here if they are needed.
- A bad outcome may occur. A bad outcome does not mean care was not appropriate.
- The anesthesiologist or treating practitioner will give me an anesthetic. I have been told about the risks of anesthesia. These include death, injury to my teeth, throat and mouth, other injury and damage to my dentures.
- I agree to get blood and/or blood products any time during this hospital stay if the treating practitioner thinks I need it. I have been told about the risk of getting blood. I have been told if there are other choices. If I need blood or blood products, I agree to the risks that include allergic reactions, infections (hepatitis and AIDS), intravascular fluid overload, and chemical imbalances.
- Parts of my body taken out during surgery can be thrown away or used for research so long as my name is not used.
- Pictures may be taken and used for teaching as long as my name is not used.
- I have talked with the treating practitioner about the procedure, why I need it, the expected outcome, the risks, the chances of success, risks, benefits and results of other treatments, and what could happen if I do not have the procedure.
- I have been told about other choices, including not having the procedure, other procedures, medicine, and therapy.
  Other choices: _____
  _____
- I have been told about the risk of the procedure, which include but are not limited to bleeding, infection, injury, scarring, damage to parts of my body, and death. Other risks: _____
  _____
  _____

_____
Signature of Patient/Surrogate

_____
Time Signed Date Signed

_____
If Signed by Surrogate, Relationship to Patient

OPTIONAL

_____
Additional Adult Witness Signature

_____
Time Signed Date Signed

TREATING PRACTITIONER USE ONLY

I have discussed with the patient the nature of the proposed care, treatment, services, medications, interventions or procedures; the potential benefits, risks or side effects, including potential problems related to recuperation; the likelihood of achieving care, treatment and service goals; the reasonable alternatives to the proposed care, treatment and service; the relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services; and when indicated, any limitations on the confidentiality of information learned from or about the patient.

Signed: _____ Date: _____ Time: _____

DOCUMENTATION OF EMERGENT/URGENT PROCEDURE

This procedure was performed emergently.

Signed: _____ Date: _____ Time: _____

INDIANA UNIVERSITY
DEPARTMENT OF PEDIATRICS
School of Medicine

CONSENT FOR ORTHO EVRA

Instructions: Place your initials after each line to indicate that you have read, understood, and agree with the statement. If you have any questions as you read, we will be happy to answer them.

___ I have been given information on other forms of birth control and I have had all of my questions answered. I have voluntarily chosen the Ortho Evra contraceptive patch as my method of birth control.

___ I have been informed that I must use the contraceptive patch correctly in order to prevent pregnancy. It is 97- 99% protective. In other words, 1-3 women out of 100 will become pregnant after using the patch for one year. Incorrect use of "the patch" will increase the risk of pregnancy.

___ I understand that the contraceptive patch will not prevent infection. I need to have my partner(s) use condoms to prevent possible infection with sexually transmitted disease, include HIV/AIDs.

___ I understand that it is important to inform my health care provider and/or nurse of all medications I am taking. This includes prescription drugs and over the counter medications.

___ I understand it is common to experience breast tenderness, nausea, dizziness, and spotting during the first three (3) months of using the contraceptive patch. These possible side effects improve with time.

___ I understand that besides preventing pregnancy, the contraceptive patch also has such benefits as decreasing blood flow and cramps with my period, regulating my periods and may also improve acne.

___ I understand that by using the patch, there may be some protection from having difficult periods, ovarian cysts, ovarian and endometrial cancer, pelvic inflammatory disease, anemia, premenstrual syndrome, and mid-cycle pain.

___ I have been informed of the **possible** side effects of the contraceptive patch:
- Nausea
- Aggravation of acne
- Breast tenderness
- Depression
- Increase in yeast infections
-Weight gain
- Skin irritation at the patch site

___ I understand that the contraceptive patch may also be associated with **minimal** risk for:
- Increased cholesterol (HDL "good cholesterol")
- Blood clots of lungs or legs
-Increase in blood pressure
- Gall bladder disease
- Liver Tumors

___ I understand that if my weight is over 200 pounds the risk of pregnancy may be higher than in a woman who is less that 200 pounds.

___ I understand that serious health problems related to use of "the patch" are **rare** but may occur. Therefore, I agree that if I have any of the following danger signs, I will call the clinic, contact my health care provider, or go to the emergency room for **immediate** care:
- Severe abdominal pain
- Chest pain
- Severe headache
- Yellowing of skin/eyes
- Visual changes
- Severe leg pain
- One-sided body weakness and/or numbness

___ I understand that the risk to life and health is greater from pregnancy than from use of the contraceptive patch.

___ I have had the opportunity to read the Ortho Evra fact sheet, discuss the risks and benefits of using "the patch" and review any questions or concerns I have with my health provider. I understand the importance of routine follow-up care or any time I am experiencing a problem. I am aware of the need for an Annual Physical exam.

_____/_____ _____/_____
Patient Signature Date Staff Signature Date

Is Gender Affirming Care Safe & Effective

- Gender Affirming care is safe, effective, and important to the health and well-being of transgender people. This life-saving care encompasses both social affirmation (e.g., supporting a transgender person's chosen name, dress etc.) and medical affirmation, which allows transgender people to live in a body that matches the gender with which they identify.
- Expert medical standards of care on the provision of gender-affirming care have been continuously maintained and updated for more than 40 years. These standards require providers to carefully evaluate each patient and make decisions in the patient's best interest.
- Every major U.S medical and mental health organization, including the American Medical Association, American Academy of Pediatrics, Federation of Pediatric Organizations, and American Psychological Association, supports access to gender affirming support and care for transgender young people and adults.
- Researchers and health experts have studied the effects of gender-affirming care for decades. The scientific evidence shows that transgender people who have access to the care they need see a positive impact on their mental and physical health. (See further detail below.)

Standards of Care for Gender Affirming Care

- Every person has unique health needs, including transgender people. Health care providers follow well-established expert best practices to prescribe age-appropriate gender-affirming support and care.
    - For prepubertal children, the only intervention is social support, such as wearing different clothes or using a chosen name. Social support (sometimes called social transition) can help kids understand and explore their gender as they grow up and is endorsed by the American Academy of Pediatrics, which is the national expert medical society for pediatricians. Social transition is entirely reversible.
    - For adolescents with clinically recognized gender dysphoria who have just started or are well into puberty, the first step in medical gender affirmation is typically the use of medications that temporarily pause puberty, otherwise known as puberty blockers. These medications have been used to treat both transgender and non-transgender young people experiencing puberty at the wrong time for more than 30 years and have been shown to be safe and effective.[i]
    - Puberty delay medications can be stopped at any time, and puberty starts back up after being temporarily paused.
    - If an adolescent continues to experience gender dysphoria, gender-affirming hormones are often used to help bring the person's body into alignment with their gender. Gender-affirming hormone therapy has been safely and effectively used for both transgender and non-transgender people.

- It is recommended that genital surgeries (commonly referred to as "top" or "bottom" surgeries) should not be carried out until (i) patients reaches the legal age of majority, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity.[ii]
- Mental health professionals are an integral part of gender affirmation for transgender youth to make sure that young people and their families feel safe and supported.

Substantial Scientific Evidence Supports Access to Gender-Affirming Care

- Recent research found that 98% of transgender youth who begin gender affirming medical treatment in adolescence continue gender-affirming medical care into young adulthood.[iii] This adds to the vast body of scientific evidence demonstrating that gender-affirming care is essential for improving the mental health and overall well-being of transgender people.

- Other studies have found similar positive impacts[iv] on the mental health of transgender and nonbinary youth.
  - Example: A 2018 review of over 50 research studies indicated that gender-affirming health care services are associated with better mental health for transgender people, including reduced suicide attempts, less depression, and higher life satisfaction.
  - Example: A 2022 review of over 50 studies found reduced rates of suicide attempts, anxiety, depression, and symptoms of gender dysphoria along with higher levels of life satisfaction, happiness, and quality of life after gender affirming surgery among transgender adults.
  - Example: A 2022 peer-reviewed study found that receipt of gender affirming care among young people aged 13 to 20 was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12-month follow-up.
  - Example: A 2021 peer-reviewed study found that transgender and nonbinary adolescents (those that don't identify with one particular sex) with access to gender affirming hormone therapy treatments had nearly 40% lower odds of having had a suicide attempt in the past year, compared to peers who did not have access to affirming care.
  - Example: A 2022 review of 16 studies on gender affirming care for transgender youth found that this care results in favorable mental health outcomes.
  - Example: A 2016 peer-reviewed study showed that transgender youth who were socially supported in their gender identity had much better mental health than those who were not supported in their identity.

Gender Affirming Care Services at Riley Hospital for Children

- At Riley, all gender affirming Care interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria. (NOTE: Gender Dysphoria is defined as the distress and unease experienced if the gender identity and sex at birth are not completely congruent.)
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- As discussed above, puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.
- Consistent with current standards of care in the U.S. , Riley does not conduct top or bottom surgeries on any patient before the age of 18. These guidelines exist to ensure that patients receive the individualized and age-appropriate care they need in consultation with their families and their doctors.

Gender Affirming Interventions for *Pediatric Patients* (less than 18yo) at Riley Hospital for Children

Services Provided	Services NOT Provided
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430465/#CIT0061

[ii] SOC V7_English.pdf (wpath.org), see page 21

[iii] Van der Loos, M. A. T. C., Hannema, S. E., Klink, D. T., den Heijer, M., & Wiepjes, C. M. (2022). Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: A cohort study in the Netherlands. The Lancet Child & Adolescent Health, 6(12), 869–875. https://doi.org/10.1016/s2352-4642(22)00254-1

[iv] Ramos, G. G. F., Mengai, A. C. S., Daltro, C. A. T., Cutrim, P. T., Zlotnik, E., & Beck, A. P. A. (2021). Systematic Review: Puberty suppression with GnRH analogues in adolescents with gender incongruity. Journal of Endocrinological Investigation, 44(6):1151-1158. doi: 10.1007/s40618-020-01449-5

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Gender Care Services

- Approximately 0.7% of adolescents (13-17) identify as transgender or gender fluid. This means they do not identify with the gender they were assigned at birth.[i]
- Transgender youth face marginalization and marked health disparities not due to their gender identities, but due to discrimination, societal stigma, lack of social support, and lack of access to gender-affirming care.[ii]
- Medical intervention for gender affirmation, when it is clinically and developmentally appropriate, is supported by solid medical evidence.[iii] These interventions can include:
    - Social Transitions: name change, change in dress, etc.
    - Medication (hormone blockers, menstrual regulation, or gender affirming hormones), and
    - Surgery [iv]
- Transgender youth have high rates of depression (12.4-64% range), self-harm (13-53%), and suicide attempts (9.3-30%). Transgender children who socially transition, and adolescents who receive medical treatment, return to the same risk of depression or anxiety as cisgender (non-transgender) children.[v]
- Not all adolescents desire gender affirming hormones, and only a small minority consider surgery of any kind in the future once they are adults.[vi]
- At Riley, all interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria.
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- Puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.

Gender Care Interventions for Pediatric Patients (less than 18yo) & Riley Hospital for Children

Services Provided at Riley	Services NOT Provided at Riley
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

Cox Exhibit 8 5/31/23

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[i] https://williamsinstitute.law.ucla.edu/wp-content/uploads/Age-Trans-Individuals-Jan-2017.pdf

[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802845/

[iii] https://www.wpath.org/publications/soc

[iv] Wylie C Hembree, Peggy T Cohen-Kettenis, Louis Gooren, Sabine E Hannema, Walter J Meyer, M Hassan Murad, Stephen M Rosenthal, Joshua D Safer, Vin Tangpricha, Guy G T'Sjoen, Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

[v] https://www.sciencedirect.com/science/article/abs/pii/S1054139X1630146X#preview-section-snippets

[vi] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8754307/

Demographic and temporal trends in transgender identities and gender confirming surgery - PMC (nih.gov)

Gender Affirming Support and Education:

Community Organizations for Support:

1. Indiana Youth Group
2. GenderNexus
3. TransSolutions
4. GEKCO
5. Trans Parent USA
6. The Trevor Project
7. PFLAG
8. Gender Spectrum

Creating A Safe Folder/ Supporting Gender Expansive Loved Ones:

9. Safe Folder (imatyfa.org)
10. Our Trans Loved Ones: Questions and Answers for Parents, Families, and Friends of People who are Transgender and Gender Expansive

History of Gender Non Conformity across cultures:

11. https://historicengland.org.uk/research/inclusive-heritage/lgbtq-heritage-project/trans-and-gender-nonconforming-histories/
12. https://screenshot-media.com/politics/lgbtqi-rights/non-binary-cultures/
13. https://www.pbs.org/independentlens/content/two-spirits_map-html/
14. https://www.lgbthealth.org.uk/lgbt-health-blog/transgenderism-in-ancient-cultures/

Gender Affirming Legal Support:

Changing Name and Gender Markers:

15. https://www.indianalegalservices.org/LGBTVAP
16. Name change scholarship (Translifeline.org)

Gender Nonconforming Student Rights:

17. Transgender Students: Know Your Rights | ACLU of Indiana (aclu-in.org)

Gender Affirming Social Supports:

Binding:

18. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3539.pdf
19. Binding: Resources & info about safer chest binding by Point of Pride
20. Safer Binding (callen-lorde.org)
21. Indiana Youth Group Binding Resources
22. Sizing for Binders
23. Chest binder donations

Packing:

24. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3637.pdf
25. https://www.prideinpractice.org/articles/packers-stand-to-pee/

Gender Affirming Medical Care:

Puberty Blockers:

26. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe2572.pdf
27. Puberty Blockers at Seattle Children's - YouTube
28. Mary Bridge Puberty Blockers Handout

Hormone Replacement Therapy- Testosterone:

29. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe2707.pdf
30. Lurie Children's- Testosterone
31. Masculinizing Hormone Therapy at Seattle Children's - YouTube

Menstrual Suppression:

32. Seattle Children's- Menstrual Hygiene for Gender Diverse Youth
33. Seattle Children's- Menstrual Suppression

Fertility Preservation:

34. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3359.pdf
35. Fertility Preservation for Trans and Gender Non-Conforming People

A Guide to Feminizing Hormones

Gender Affirming Care

Hormone therapy is an option that can help transgender people feel more comfortable in their bodies. Like other medical treatments, there are benefits and risks. Knowing what to expect will help us partner to maximize the benefits and minimize the risks.

The binary term “male,” “female,” “masculine,” “feminine,” “masculinizing” and “feminizing” do not accurately reflect the diversity of people’s bodies or identities. To describe how hormones work, it is helpful to know how testosterone works in non-intersex, non-trans men’s bodies, and how estrogen and progesterone works in non-intersex, non-trans women’s bodies. We keep these binary terms in quotes to emphasize that they are artificial and imperfect concepts.

What are hormones?

Hormones are chemical messengers that tell tissues of the body how to function, when to grow, when to divide and when to die. They regulate many functions, including growth, sex drive, hunger, thirst, digestion, metabolism, fat burning and storage, blood sugar, cholesterol levels and reproduction.

What are sex hormones?

Sex hormones are involved in the development of the penis and testicles, or the vulva and clitoris (external genitals). Sex hormones also affect the secondary sex characteristics that typically develop at puberty (facial and body hair, bone growth, breast growth, voice changes, etc.). There are 3 categories of sex hormones in the body:

- **Androgens:** testosterone, dehydroepiandrosterone (DHEA), dihydrotestosterone (DHT)
- **Estrogens:** estradiol, estriol, estrone
- **Progestin:** progesterone

Generally, people with testicles tend to have higher androgen levels, and people with ovaries tend to have higher levels of estrogens and progestogens.

What is hormone therapy?

Hormone therapy is taking medicine to change the levels of sex hormones in your body. Changing these levels will affect your hair growth, voice pitch, fat distribution, muscle mass and other features that are associated with sex and gender. Feminizing hormone therapy can help make the body look and feel less “masculine” and more “feminine” — making your body more closely match your identity.

To Learn More

- Adolescent Medicine - 206-987-2028
- Gender Clinic Care Navigator 206-987-8319
- Ask your child’s healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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What medicines are involved?

There are different kinds of medicines used to change the levels of sex hormones in your body. These medicines work by affecting:

- The part of your brain that stimulates sex hormone production
- Your testicles (which produce testosterone)
- The cells in your body that respond to sex hormones

Usually, feminizing hormone therapy involves:

- Estrogen
- A medicine to block testosterone
- A combination of estrogen and a medicine to block testosterone
- Sometimes a progestin is added

Estrogen

Estrogen is the main hormone responsible for promoting “feminine” physical traits. It works directly on tissues in your body (for example, makes breasts develop). Estrogen also indirectly reduces testosterone. Estrogen can be taken by:

- Pill (oral or under the tongue)
- Injection (intramuscular or subcutaneous)
- Skin patch or gel (transdermal)

There are different formulations of estrogen. Your healthcare provider will talk to you about the different kinds and what is right for you.

Androgen blockers

Androgen-blockers work by blocking testosterone. They are also known as anti-androgens or androgen antagonists. They reduce “masculine” physical traits and have a mildly “feminizing” effect. For example, they will help slow “male” pattern baldness, reduce growth of facial hair and stop spontaneous/morning erections.

There are different types of androgen blockers. The one most typically prescribed is spironolactone. Androgen blockers are often prescribed in addition to estrogen because they have effects that complement each other. Taking androgen blockers reduces the amount of estrogen you need to get the same effects, which minimizes the health risks associated with estrogen. Androgen blockers can be prescribed alone for people who want to reduce “masculine” characteristics for a more androgynous appearance because it is less “feminizing” than estrogen.

Progestins

There are mixed opinions about using progestins for feminizing hormone therapy. Some gender clinic programs choose not to use progestins due to the lack of clear evidence that they facilitate “feminization.” Progestins also have known side effects (which include depression, weight gain and changes to blood fats).

However, progestins may be used by some gender care providers in the following situations:

- If estrogen alone is not working, even at the maximum dose.
- As a replacement for estrogen if there are concerns about the side effects or risks of estrogen.
- To promote nipple and breast development (but there is not strong evidence for this yet).

As with estrogen and androgen blockers, balancing possible risks and benefits of progestins is a decision between you and your healthcare providers.

What is a typical dose?

Feminizing hormone therapy varies greatly from person to person. There is no right hormone combination, type, or dose for everyone. Deciding what to take depends on your health because each hormone therapy has different risks and side effects. What your healthcare provider prescribes depends on what is available locally and what you can afford. It may also depend on insurance coverage.

It can change based on how your body reacts when you start taking hormones — everyone's body is different and sometimes people have a negative reaction to a specific kind of medicine.

The right dose or type of medicine for you might not be the same as for someone else. It is a good idea to discuss the advantages and disadvantages of different options with us. If you have any concerns about being able to take the medicines — or about the side effects, costs or health risks — let us know. We take your needs and concerns into account when planning your hormone therapy.

We will partner with you to explore your insurance coverage and any other resources to make sure you get the care you need.

In prescribing a specific medicine and dose, we consider your overall health, including any other medicines you are taking. Every person is different — each body absorbs, processes and responds to sex hormones differently. Some people show more changes than others. Changes happen more quickly for some than others.

Taking more hormones than the dose you were prescribed will not speed up changes. Taking more than your prescribed dose greatly increases your health risks.

If you think your dose is too low, talk with us to discuss your options. It might be better to try a different type of medicine or a combination of medicines, rather than increasing the dose.

If you have your testicles removed, your body will only produce a tiny amount of testosterone, so:

- The dose of estrogen can be reduced
- Androgen blockers can be reduced or stopped

You will need to stay on estrogen or another form of medicine for the rest of your life to keep your bones strong. We may also suggest you take low-dose testosterone to help your metabolism. Your provider may also suggest that you take calcium and vitamin D supplements to protect your bones.

What changes can I expect?

Feminizing hormone therapy has important physical and psychological benefits. Bringing mind and body closer together eases gender dysphoria and can help you feel better about your body. People who have had gender dysphoria often describe being less anxious, less depressed, calmer and happier when they start taking hormones. For some people, this psychological change happens as soon as they start taking hormones. For others, it happens a bit later as the physical changes appear more.

Each person changes differently. How quickly changes appear for you depend on:

- Your age
- The number of hormones receptors in your body
- The way your body responds to the medicine

There is no way to know how your body will respond before you start hormones.

Androgen blocker (spironolactone) without estrogen

Taking spironolactone (the most common androgen blocker) without estrogen has small effects. The changes are caused by the medicine blocking the effect of testosterone in your body. Most of the changes are reversible, which means if you stop taking it, your body will go back to how it was before you started taking the medicine. Androgen blockers affect the whole body. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 3 months	• Decreased sex drive • Fewer instances of waking up with an erection or spontaneously having an erection. Some people also have difficulty getting an erection even when they are sexually aroused • Decreased ability to make sperm and ejaculatory fluid
Gradual changes (usually takes at least 2 years)	• Slower growth of facial or body hair • Slowed or stopped “male”-pattern balding • Slight breast growth (reversible in some cases, not in others)

Estrogen

Taking estrogen has stronger physical "feminizing" effects. These changes are caused by the estrogen's effect on cells in your body that have estrogen receptors. Taking estrogen also has an indirect effect of suppressing testosterone production. Like androgen blockers, estrogen affect the whole body. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 6 months	• Softening of skin • Less muscle mass and more body fat • Redistribution of body fat to be more on breasts and hips • Possible decrease in sex drive • Fewer instances of waking up with an erection or spontaneously having an erection. Some people also have difficulty getting an erection even when they are sexually aroused. • Decreased ability to make sperm and ejaculatory fluid
Gradual changes (maximum changes after 2 to 3 years)	• Nipple and breast growth • Slower growth of facial and body hair • Slowed or stopped "male" pattern balding • Smaller testicles

Breast and nipple growth starts early but is usually gradual. It can take 2 years or more for breasts to reach their maximum size. As with all people, there is a range in how large breasts grow. In many cases, your breasts might not grow beyond an A or B cup size. If you are not happy with the size of your breasts after 18 to 24 months on estrogen, you can consider surgical augmentation. The implants will look most natural if you wait to get as much growth as you can from hormones.

Most of the effects of hormones happen in the first 2 years. During this time, the doctor who prescribes your hormones will usually want to see you every 3 months. This is to check if the hormones are working properly. After that, you will probably need an appointment every 6-12 months. At appointments in the first 2 years, your doctor will likely:

- Look at your facial and body hair. If you shave, the doctor will ask how quickly your hair grows back.
- Ask about changes to your sex drive, erections, or other sexual changes.
- Ask about breast growth or nipple changes
- Order blood test to see what your hormone levels are.
- Ask how your feel about the changes that have happened so far.

After 2 years, your doctor will monitor the effects by asking if you notice any more changes from the hormones.

When you are 21 years old, you will transition to a medical provider who can continue your treatments as an adult. For information about moving to an adult healthcare provider, visit seattlechildrens.org/TransitioningToAdultHealthcare.

Are the changes permanent?

Some of the changes you will notice from the feminizing hormone therapy are not permanent. If you stop taking the medicine, some of the changes will stop and your body will return to how it was before you started the hormones. There are 3 types of changes that may be permanent:

- Breast growth
- Fertility
- Fat distribution to hips

Breast growth

If you are taking the androgen blocker called spironolactone without estrogen because you do not want visible changes, you might see some breast growth. This growth happens slowly, so you can stop taking it if you do not want breast growth. Breast growth from spironolactone is usually small and reversible. But in some people, the breast tissue remains even after the spironolactone is stopped.

Estrogen causes permanent nipple development and breast growth. Even if you stop taking estrogen, the breast tissue will not go away and your nipples will not shrink.

Fertility

Both androgen blockers and estrogen affect your production of sperm, which means you may have trouble having biological children after taking them. It is also important to know that we do not yet fully understand the long-term effects feminizing medications have on fertility. If you stop taking feminizing hormones, your ability to make sperm may or may not return to what it was before you started. We strongly recommend that you talk about options for sperm banking before starting hormone therapy. If you have already started hormones, you can work with your doctor to stop the hormones, give sperm samples and store them if they are viable. Then you could go back on hormones.

Although androgen blockers and estrogen affect sperm production, there may still be a chance you could make someone pregnant after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.**

Hormone therapy does not lower your risk of HIV and other sexually transmitted infections. Depending on how you have sex, you may need to use condoms, gloves or other latex barriers. Feminizing hormones can make erections less firm, increasing the risk of condom leakage. In this situation, your partner can use a special condom they put inside their anus or vagina. They are called “female condoms,” but can be used by people of any gender.

What are the risks?

The medical effects and safety of feminizing hormone therapy are not fully understood. Most of the studies on hormone therapy involve different doses than are used for gender affirming care. There may be long-term risks that are not known yet.

We can lower many of the known risks of feminizing hormone therapy by creating a hormone combination that is made just for you. There are also actions you can take to reduce the risks, including:

- Not smoking. This is the number one thing you can do to reduce your risk of blood clots and heart disease. Even the occasional smoker is at an increased risk. If you do not smoke it increases the amount of estrogen that we can prescribe safely.
- Having your blood tested as recommended by your doctor.

Social repercussions

Being a person in a transphobic society can have social risks. Some people experience violence, harassment and discrimination, while others have lost support of loved ones. If you are worried about how others might react to the changes that come with hormone therapy, counseling can be useful. If you are looking for a therapist, see "How to Find a Therapist." seattlechildrens.org/pdf/PE2195.pdf.

Blood clots

Taking estrogen increases the risk of blood clots. Blood clots can cause death, permanent lung damage (clot in the lungs), permanent brain damage (stroke), heart attack or chronic problems with veins in your legs. The risk of blood clots is much higher for if you smoke.

The danger is so high that some doctors will not prescribe estrogen if you smoke, even occasionally. Most healthcare providers will prescribe you only a low dose of estrogen until you fully stop smoking. The risk of blood clots can be made lower by:

- Taking estrogen by skin patch or gel (transdermal)
- Taking estrogen under the tongue (sublingual)
- Taking estrogen by injection (intramuscular or subcutaneous)
- Using a lower dose of estrogen

Taking estrogen changes the way your body uses and stores fat. Taking estrogen can increase deposits of fat around your internal organs. This type of fat is associated with an increased risk for diabetes and heart disease. Estrogen also increases the risk of gallstones, which can block your gallbladder. See a medical professional right away if you have these symptoms of gallstones:

- Chest, leg or abdominal pain
- Any swelling (edema) in your legs

If you have the following symptoms for more than a couple of days, call a healthcare professional:

- Nausea and vomiting (similar to morning sickness in pregnant women)
- Frequent headaches or migraines, if the pain is unusually bad or if you are vomiting

High blood pressure

Estrogen can also cause an increase in blood pressure. This can be avoided by taking estrogen with an androgen blocker medicine (spironolactone) that lowers blood pressure. If you cannot take spironolactone, you can make other changes to reduce your risk. This includes other types of medicine, exercise, not smoking and changes to your diet.

Galactorrhea and prolactinoma

With breast growth, there is often an increase in milky discharge from the nipples. This is called galactorrhea. This is caused by the estrogen stimulating the production of the hormone prolactin, which stimulates breast ducts to make milk. We do not know if milk production increases the risk of noncancerous tumors (prolactinoma) of the pituitary gland.

Although prolactinoma is not usually life-threatening, it can damage your vision and cause headaches. For this reason, your doctor will monitor for signs of prolactinoma regularly for at least 3 years after you start taking estrogen. More tests can be ordered if your prolactin level is high or if prolactinoma is suspected.

Breast cancer

It is not known if estrogen causes an increased risk of breast cancer. There have been cases of people who have developed breast cancer after hormone therapy for gender affirming care. Talk with your healthcare provider about screening tests that can be done to catch early signs of breast cancer. Your breast cancer risk is higher if you:

- Have a family history of breast cancer
- Have been taking estrogen or progestin for more than 5 years
- Are 50 years or older
- Are overweight

Kidney health

Spironolactone (the most common androgen blocker) affects the balance of water and salt in the kidneys. If the amount of water and salt gets out of balance, you can have problems with low blood pressure. Rarely, this imbalance can lead to high levels of potassium in your body, which can cause changes in heart rhythm that can be life-threatening. Your blood tests will check your potassium levels and kidney function on a regular basis. This is especially important if you:

- Have a history of kidney problems
- Are taking medicine that can raise blood potassium (ask your doctor or pharmacist)
- Are taking ACE-inhibitors (commonly prescribed for people with high blood pressure or heart problems).

If you receive care from another healthcare provider, tell them you are on hormone therapy, so you do not take these kinds of medicines unknowingly.

Migraine headaches

Migraine headaches may happen more often after starting estrogen. People with a history of migraines may want to begin therapy at lower estrogen doses and increase doses slowly. Please talk with your provider if you develop new or different migraines after starting estrogen.

Skin rash

The skin patch (transdermal application) of estrogen can sometimes cause a skin rash. The androgen blocker spironolactone can also cause a skin rash. If this happens, contact us.

How do I get the most benefit and minimize risks?

You can help make hormone therapy as effective and safe as possible. Here are steps you can take:

- **Be informed.** Understanding how hormones work, what to expect, and possible side effects and risks will give you the tools to be in charge of your health and make informed decisions. Do your own research and ask questions. To get started, see "Gender Clinic Booklist and Resources" seattlechildrens.org/pdf/PE2634.pdf.
- **If you smoke, stop or cut down.** Any smoking greatly increases the risks of hormone therapy. If you are a smoker, your estrogen level may be kept low. If you need help to quit smoking, we can help you develop a plan or direct you to resources. You can contact QuitNow quitnow.net/Program/ as a first step. If you are not quite ready to quit, consider cutting down. Every little bit helps.
- **Find a healthcare provider you trust and can be honest with.** To get the most from hormone therapy, you need to be able to talk openly about what you want, concerns you have, and problems you are experiencing. You should feel comfortable to talk openly with your healthcare provider about your health history, smoking, alcohol, street drugs, dietary supplements, herbs and any other medicines you are taking. Hormone therapy can be affected by all of these things. Being honest with your healthcare provider will help the provider to create a hormone plan that is right for you.
- **Deal with problems early on.** If caught early enough, most of the problems that can result from hormone therapy can be dealt with in a creative way that does not involve stopping hormone therapy. Waiting to talk with your provider can make the problem worse.
- **Do not change medicine on your own.** Check with your healthcare provider if you want to start, stop or change the dose of any of your medicines. Taking medicine more often or at a higher does than prescribed increases health risks and can slow down the changes you want. If you want to change your medicine, talk with your provider first.
- **Take a holistic approach to your health.** Health involves more than just hormone levels, and taking hormones is only one way for you to improve your quality of life. Building a circle of care that includes health professionals, friends, partners and other people who care about you will help you to deal with problems as they come up. This support will help you to heal from societal transphobia.
- **Know where to go for help.** The Seattle Children's Gender Clinic can help you find information on health and transition issues. We can also help you connect with support groups and community resources. We can help with referrals if you need assistance finding other medical providers, counselors or another type of health professional.

What will not change?

Body image

Many people experience an increase in self-esteem and confidence as their body changes with hormones. You might find that there are also unrealistic societal standards after hormone therapy. It can be hard to separate gender dysphoria from body image problems. Professional and peer counseling can help you sort through your expectations about your appearance and work toward self-acceptance.

Mental health

Many people experience positive emotional changes from hormone therapy, including decreased gender dysphoria. Hormone therapy might help you to become more accepting of yourself, but life can still present emotional and social challenges. Biological factors, stresses of transphobia and unresolved personal issues can also affect your mental health. It is important to continue to access counseling, medication and other supports as needed for your mental health.

Your community

Some people hope that they will find greater acceptance after they make physical changes. Seek support from people and communities who accept and respect you as your body, gender identity and expression evolve. It can be helpful to connect with other transgender people, while remembering that no one will exactly mirror your own experience, identity and beliefs. It can be common to feel lonely and alone after starting hormone therapy. Having a support network to turn to can help.

Your body

Hormone therapy does not affect some parts of the body. Some changes are very small. Parts of the body that will not change:

- Penis
- Vagina
- Sex chromosomes
- Adam's apple
- Bone structure
- Voice pitch
- Height

Hormone therapy can make facial and body hair grow more slowly and be less noticeable, but hair will not go away completely. Some people get laser treatment or electrolysis to get rid of facial hair. Laser hair removal works best if you have light skin and dark hair. Electrolysis destroys the follicle that the hair grows out of, so it is permanent hair removal. Electrolysis works for all people.

While "male" pattern baldness may slow down or stop, bald areas will not grow hair again. Some people use wigs or hairpieces, hair transplants or other medical treatments, like Minoxidil (Rogaine).

Feminizing hormone therapy does not change how high or low your voice is (pitch). Hormone therapy will not change your speech patterns. Speech

therapy can help change pitch and other aspects of speech associated with gender. Some people have surgery on their vocal cords or the surrounding cartilage to try to make their voice sound higher.

Once your bones have stopped growing after puberty, feminizing hormone therapy cannot change the size or shape of your bones. Some people use facial feminizing surgery to change the shape of the skull and facial features, and to reduce a prominent Adam's apple. After puberty, there are no treatments you can take to change your height or the size of your hands and feet.

How often do I need to come in for appointments?

You need regular physical exams and lab tests to monitor your overall health while you are on hormone therapy. The first year after starting hormones, this will be at least every 2 to 3 months.

What will happen at appointments?

At every appointment, we will:

- Ask questions about your overall health
- Check your blood pressure, check your weight and listen to your lungs
- Look at your arms, legs, hands and feet to check your overall circulation and look for any signs of swelling, fluid retention or pain
- Check for early warning signs of health problems that can be caused by hormone therapy (blood clots, heart disease, diabetes)
- Recommend blood tests
- Recommend other tests (such as bone scans, heart stress function tests) as needed, depending on your health history, age and any signs of possible health problems
- Starting at age 40, but also depending on your age, family history and other risks for breast cancer, you may need an examination of your breast tissue (mammogram). When you are over 50, your healthcare provider should discuss checking for prostate cancer.

While gender healthcare training for providers emphasizes the need to be creative and stopping hormones only as a last resort, there are some health problems that make it dangerous to take hormones, such as uncontrolled heart disease. If your healthcare provider suspects you have one of these health problems, we will try to control it through medical treatment and changes to your diet or exercise routine. If the condition cannot be controlled, your provider may switch you to another type of hormone or reduce or stop your dose until your other health problems can be controlled.

Resources

Feminizing Hormone Therapy at Seattle Children's (video, 3:12)
youtu.be/8_gdLCXKI5Y

Excellence for Transgender Health - transhealth.ucsf.edu

12/20
PE2706

A Guide to Masculinizing Hormones

Gender Affirming Care

Hormone therapy is an option that can help transgender people feel more comfortable in their bodies. Like other medical treatments, there are benefits and risks. Knowing what to expect will help us partner to maximize the benefits and minimize the risks.

The binary terms “male,” “female,” “masculine,” “feminine,” “masculinizing” and “feminizing” do not accurately reflect the diversity of people’s bodies or identities. To describe how hormones work, it is helpful to know how testosterone works in non-intersex, non-trans men’s bodies, and how estrogen and progesterone works in non-intersex, non-trans women’s bodies. We keep these binary terms in quotes to emphasize that they are artificial and imperfect concepts.

What are hormones?

Hormones are chemical messengers that tell tissues of the body how to function, when to grow. They regulate many functions, including growth, sex drive, hunger, thirst, digestion, metabolism, fat burning and storage, blood sugar, cholesterol levels and reproduction.

What are sex hormones?

Sex hormones are involved in the development of the vulva and clitoris, or the penis and testicles (external genitals). Sex hormones also affect the secondary sex characteristics that typically develop at puberty (facial and body hair, bone growth, breast growth, voice changes, etc.). There are 3 categories of sex hormones in the body:

- Androgens: testosterone, dehydroepiandrosterone (DHEA), dihydrotestosterone (DHT)
- Estrogens: estradiol, estriol, estrone
- Progestin: progesterone

Generally, people with testicles tend to have higher androgen levels, and people with ovaries tend to have higher levels of estrogens and progestogens.

What is hormone therapy?

Hormone therapy is taking medicine to change the levels of sex hormones in your body. Changing these levels will affect your hair growth, voice pitch, fat distribution, muscle mass and other features that are associated with sex and gender. Masculinizing hormone therapy can help make the body look and feel less “feminine” and more “masculine” — making your body more closely match your identity.

To Learn More

- Adolescent Medicine 206-987-2028
- Gender Clinic Care Navigator 206-987-8319
- Ask your child’s healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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What medicines are involved?

Testosterone (sometimes called "T") is the main hormone responsible for promoting "masculine" physical traits and is usually used for hormonal "masculinization." Testosterone works on tissues in your body (such as stimulating growth of your clitoris). Testosterone alone will eventually stop menstrual cycles, but to stop menstrual cycles immediately, there are treatments that can be used to stop your period. Examples are injecting Depo-Provera (a type of progestin) every 3 months, Nexplanon (implant under the skin in the arm), an IUD (intrauterine device), daily pills with or without estrogen.

How do you take it?

Testosterone can be taken in different ways:

- Injection (subcutaneous application)
- Skin patch, cream or gel (transdermal application)

What are the differences in the ways to take it?

The way you take testosterone seems to affect how fast the changes happen. Using a patch, cream or gel takes slightly longer than injection to make menstrual periods stop and to make facial and body hair grow. Using a skin patch, cream or gel to take testosterone means a steady level in your blood. With injection, there is a peak right after injecting and a dip at the end of the injection cycle. This can increase side effects at both ends of the cycle (aggression/mood swings when testosterone peaks, and fatigue/irritability/mood swings when testosterone dips). This can be reduced by injecting once a week instead of every other week, or by switching to a skin patch, cream or gel.

What is a typical dose?

Testosterone therapy varies greatly. Deciding what to take depends on:

- Your health (each type of testosterone has different risks and side effects)
- What is available where you live
- What you can afford (what your insurance covers)
- How your body reacts when you start taking testosterone (every person is different, and some people have a negative reaction to a specific kind of brand or formulation)
- Your gender goals

The right dose or type of testosterone for you may be different than for others. It is a good idea to talk about the different options with your Gender Clinic healthcare team. If you have any concerns about being able to take the testosterone, or about the side effects, costs or health risks, let us know. It is important that your needs and concerns be taken into account when planning your hormone therapy.

We will partner with you to explore your insurance coverage and any other resources to make sure you get the care you need.

You may need to start on a lower dose if you have not experienced any puberty, have chronic health problems, are at risk for specific side effects or have had your ovaries removed. If you have questions about the reasons for your dose, talk with us.

Every person is different in terms of how their body absorbs, processes and responds to sex hormones. Some people have more changes than others.

Changes happen more quickly for some people than others. Taking more testosterone than the dose you were prescribed — or taking another kind of steroid as well as testosterone (sometimes called "stacking") — can greatly increase your health risks. Extra testosterone in your body can be converted to estrogen. If you think your dose is too low, talk with us to discuss your options.

If you have your ovaries removed in the future, you may need a different dose of testosterone. To maintain the full effects of testosterone, you will need to stay on testosterone or another form of medicine for the rest of your life (unless you choose to go off of it). Most people will stay on the medicine. In addition, to preserve bone strength, your doctor may also suggest you take calcium and Vitamin D supplements.

What changes can I expect?

Masculinizing hormone therapy has physical and psychological benefits. Bringing the mind and body closer together eases gender dysphoria and can help you feel better about your body. People who have had gender dysphoria often describe being less anxious, less depressed, calmer and happier when they start taking hormones. For some people, this psychological change happens as soon as they start taking hormones. For others, it happens a bit later as physical changes progress. Each person changes differently. How quickly changes appear for you depend on:

- Your age
- The number of hormone receptors in your body
- How sensitive your body is to testosterone

There is no way of knowing how your body will respond before you start hormones. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 3 months	• Increased sex drive • Vaginal dryness • Growth of your clitoris (typically 1 to 3 cm) • Increased growth, coarseness and thickness of hairs on arms, legs, chest, back and abdomen • Oilier skin and increased acne • Increased muscle mass and upper body strength • Redistribution of body fat (more around waist and less around hips)
After 1 to 6 months	• Menstrual periods stop
After 3 to 6 months	• Voice starts to crack and drop (can take up to a year to finish changing fully)
Gradual changes (usually takes at least 1 year)	• Gradual growth of facial hair (usually takes 1 to 4 years to reach full growth) • Possible "male"-pattern balding

Most of the effects of hormones happen in the first 2 years. During this time, the doctor who prescribes your testosterone will want to see you every

2 to 3 months. This will continue until the dose that is best for you gets figured out and blood tests show you are at consistent level. After that, you will need an appointment once a year until you are 21 years old. When you are 21 years old or when you are at a stable maintenance dose and ready to switch to an adult provider, you will transition to a provider who can continue your treatments as an adult. For information about moving to an adult health care provider visit: seattlechildrens.org/TransitioningToAdultHealthcare.

- At appointments in the first 2 years, your doctor will likely:
- Look at your facial and body hair. If you shave, the doctor will ask how quickly your hair grows back.
- Ask about changes to your sex drive, clitoris or other sexual changes; menstrual period, skin and voice.
- Order blood tests check your hormone levels.
- Ask how your feel about the changes that have happened.

After 2 years have passed, you will likely just be asked if you notice any further changes from the hormones.

Are the changes permanent?

Most of the changes you will notice from the testosterone are not fully reversible, even if you stop taking testosterone.

- **Permanent (not reversible):** deeper voice, hair growth. "Male"-pattern baldness may or may not happen, based on your family history.
- **May or may not reverse:** clitoral growth, body and facial hair will decrease but usually does not completely disappear, the ability to get pregnant
- **Reversible:** menstrual periods will return and changes to fat, muscle and skin will reverse

Fertility

The long-term effects of testosterone on fertility are not fully understood. The ability to get pregnant **may not come back** even if you stop taking testosterone. Although testosterone can permanently affect your fertility, there may still be a chance you could get pregnant even after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.**

What will not change?

Body image	Many people experience an increase in self-esteem and confidence as their body changes with hormones. You might find that there are also unrealistic societal standards after hormone therapy. It can be hard to separate gender dysphoria from body image problems. Professional and peer counseling can help you sort through your expectations about your appearance and work toward self-acceptance.
Mental health	Many people experience positive emotional changes from hormone therapy, including decreased gender dysphoria. Hormone therapy might help you to become more accepting of yourself, but life can still present emotional and social challenges. Biological factors, stresses of transphobia and unresolved personal issues can also affect your mental health. It is important to continue to access counseling, medication and other supports as needed for your mental health.
Your community	Some people hope that they will find greater acceptance after they make physical changes. Seek support from people and communities who accept and respect you as your body, gender identity and expression evolve. It can be helpful to connect with other transgender people, while remembering that no one will exactly mirror your own experience, identity and beliefs. It can be common to feel lonely and alone after starting hormone therapy. Having a support network to turn to can help.
Your body shape	Hormone therapy will not change some physical characteristics, and some are only slightly changed. These include aspects of your body that develop before birth (vagina, sex chromosomes, etc.) and also physical characteristics that developed from the increase in estrogen at puberty.
Your speech patterns	Although testosterone typically makes your voice pitch drop to deeper levels, it does not change intonation and other speech patterns that are associated with gender socialization. Some people find that speech therapy can help. Speech therapy can also be useful if your pitch does not drop as much as you wanted.
Breast tissue	Testosterone may slightly change the shape of your chest by increasing muscle mass and decreasing fat. However, it does not make breast tissue go away. Some people have “top surgery,” a surgery to remove breast tissue and reshape their chest.

Bone structure

Once your bones have stopped growing after puberty, testosterone cannot change the size or shapes of your bones. There are no treatments you can take to increase your height or the size of your hands and feet.

Pregnancy and sexually transmitted infections

Although testosterone can permanently affect your fertility, there may still be a chance you could get pregnant even after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.** It is also important to note that testosterone could cause some potential harm to a fetus and current guidelines advise against taking testosterone during pregnancy.

Testosterone does not decrease the risk of HIV and sexually transmitted infections. Depending on how you have sex, you may need to use condoms, gloves or other latex barriers. Testosterone tends to make the genital tissue dryer and the cervix more fragile, so if you have frontal or vaginal sex you should add extra lubricant to avoid breaking latex or tearing your tissue.

What are the risks?

The long-term safety of testosterone is not fully understood. Most of the studies on hormone therapy involve non-trans men taking testosterone at different doses. There may be long-term risks that are not yet known.

Heart disease, stroke and diabetes

Testosterone can increase the risk of heart disease, stroke and diabetes. Testosterone tends to:

- Decrease good cholesterol (HDL) and may increase bad cholesterol (LDL)
- Increase fat deposits around internal organs and in the upper abdomen
- Increase blood pressure
- Decrease your body's sensitivity to insulin
- Cause weight gain (mostly from muscle gain)
- Increase the amount of red blood cells and hemoglobin (a red protein responsible for transporting oxygen in the blood) you have in your body

The increase in the amount of red blood cells and hemoglobin is usually remains in the same range as someone who was assigned male at birth (which does not pose health risks). Occasionally, a higher increase can happen and can lead to life-threatening problems, like stroke and heart attack. You will have regular blood tests to check red blood cell and hemoglobin levels.

The risks are greater for people who smoke, are overweight or have a family history of heart disease. Your risk of heart disease, stroke and diabetes can be reduced by creating a care plan that is specific to you. A care plan includes regular blood tests and optimizing contributing factors. These include not smoking, exercising and eating well.

Headaches and migraines

Some people get headaches and migraines after starting testosterone. If you are getting more frequent headaches or migraines or the pain is unusually bad, talk to your primary healthcare provider.

Cancer

It is not known if testosterone increases the risks of breast cancer, ovarian cancer or uterine cancer. These types of cancer are all sensitive to estrogen, called estrogen-dependent cancer. Some testosterone is converted to estrogen so your body will have estrogen even if you don't have ovaries. You are at higher risk of estrogen-dependent cancer if you have a family history of these types of cancer, are age 50 or older or are overweight. Talk with us about screening tests available for these types of cancer.

Mental health

There are often positive emotional changes from reduced gender dysphoria. However, in some people testosterone can cause increased irritability, frustration and anger. There are reports of testosterone destabilizing people with bipolar disorder, schizoaffective disorder and schizophrenia. Taking testosterone via skin patch or cream/gel (transdermal application) can be helpful if the mood swings are linked to the highs and lows of an injection cycle.

Social repercussions

Living in a transphobic society can have social risks. Some people experience violence, harassment and discrimination, while others have lost support of loved ones. If you are worried about how others might react to the changes that come with hormone therapy, counseling can be useful. If you are looking for a therapist, see "How to Find a Therapist." seattlechildrens.org/pdf/PE2195.pdf.

How do I get the most benefit and minimize risks?

You can help make hormone therapy as effective and safe as possible. Here are steps you can take:

- **Be informed.** Understanding how hormones work, what to expect, and possible side effects and risks will give you the tools to be in charge of your health and make informed decisions. Do your own research and ask questions. To get started, see "Gender Clinic Booklist and Resources" seattlechildrens.org/pdf/PE2634.pdf.
- **If you smoke, stop or cut down.** Any smoking greatly increases the risks of taking hormones. If you are a smoker, your testosterone level may be kept low. If you need help to quit smoking, we can help you develop a plan or direct you to resources. You can contact QuitNow quitnow.net/Program/ as a first step. If you are not quite ready to quit, consider cutting down. Every little bit helps.
- **Find a healthcare provider you trust and can be honest with.** To get the most from hormone therapy, you need to be able to talk openly about what you want, concerns you have and problems you are experiencing. You should feel comfortable to talk openly with your healthcare provider about your health history, smoking, alcohol, street drugs, dietary supplements, herbs and any other medicines you are taking. The risks associated with taking testosterone can be affected by all of these things. Being honest about them will help your healthcare providers to create a hormone plan that is right for you.
- **Deal with problems early on.** If caught early enough, most of the problems that can result from testosterone can be dealt with in a creative way that

does not involve stopping testosterone treatment completely. Waiting to talk with your provider can make the problem worse.

- **Do not change medicine on your own.** Check with your healthcare provider if you want to start, stop or change the dose of any of your medicines. Taking testosterone more often or at a higher does than prescribed increases health risks and can slow down the changes you want. If you want to make changes, talk with your provider first.
- **Take a holistic approach to your health.** Health involves more than just hormone levels. Taking hormones is only one way for you to improve your quality of life. Building a circle of care that includes health professionals, friends, partners and other people who care about you will help you to deal with problems as they come up. This support will help you to heal from societal transphobia.
- **Know where to go for help.** The Seattle Children's Gender Clinic can help you find information on health and transition issues. We can also help you connect with support groups and community resources. We can help with referrals if you need assistance finding other medical providers, counselors or another type of health professional.

How often do I need to come in for appointments?

As long as you are taking testosterone (possibly for the rest of your life), you will need to have regular physical exams and lab tests to monitor your overall health. The first year after starting testosterone, the doctor who prescribes your hormones will want to see you at least every 3 months; after that, you will have appointments at least every 6 months.

What will happen at appointments?

At every appointment, we will:

- Ask questions about your overall health.
- Ask questions about your mood.
- Take your blood pressure and check your weight and your heart rate.
- Check for early warning signs of health problems that can be caused by testosterone or made worse by testosterone (e.g., heart disease, diabetes).
- Recommend blood tests to check your blood sugar, blood fats, blood cells and liver health.
- Recommend other tests (e.g., bone scan, heart stress function test) as needed, depending on your health history, age, and any signs of possible health problems.

To check for early signs of cancer, as part of the physical exam, your doctor or nurse will do breast and cervical screening tests starting at 21 years old.

While gender healthcare training for providers emphasizes the need to be creative and stopping hormones only as a last resort, there are some health problems that make it dangerous to take testosterone, such as uncontrolled heart disease. If your healthcare provider suspects you have one of these health problems, we will try to control it through medical treatment and changes to your diet or exercise routine. If the condition cannot be controlled, your provider may switch you to another type of hormone, or reduce or stop your dose until your other health problems can be controlled.

Resources

Masculinizing Hormone Therapy at Seattle Children's (video, 3:37)
youtu.be/dmjSEf2og1A

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transhealth.ucsf.edu

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PE2707

Menstrual Suppression and Breakthrough Bleeding For Gender Diverse Youth

What is menstrual suppression?

Menstrual suppression is using hormone medicines to stop monthly menstrual bleeding, also known as uterine bleeding or periods.

Why choose menstrual suppression?

There are many reasons why people choose to suppress menstrual bleeding.

- Many gender diverse people are uncomfortable during their menstrual cycles, or experience intense dysphoria from them. Stopping menstrual bleeding can be vital to improving mental health and comfort in their bodies.
- For some people, menstrual bleeding can be heavy and painful, and some have irregular bleeding that is hard to control.
- There are many other medical reasons to suppress menstrual bleeding, such as chronic pelvic pain, endometriosis, polycystic ovary syndrome, headaches, bleeding disorders, and developmental delay.

Is it safe?

Yes, it is safe to control or stop menstrual bleeding using hormone medicines. People have been safely doing this since the 1960s. It does not cause harm to your body.

The medicine and methods may have some side effects and risks. You can discuss them with your healthcare provider.

How long will it take?

All the options for menstrual suppression will take some time to shorten the length and heaviness of menstrual bleeding. For the first few months, you might have some unpredictable menstrual bleeding, but the bleeding will generally lighten or stop over time.

If you are not getting enough menstrual suppression after 2 to 3 months, you can talk to your provider about trying other options.

Can this be used at the same time as testosterone?

Yes, menstrual suppression medicines can be used with testosterone. Testosterone alone often causes menstrual bleeding to stop after about 6 months. You can start one of these medicines before starting testosterone to stop menstrual bleeding sooner, or after starting testosterone if you are still having menstrual bleeding while taking testosterone.

What are the options?

There are many hormone medicine options for controlling and suppressing menstrual bleeding. Discuss the options you would prefer with your healthcare provider, and they can give you a prescription. See the table below.

Unfortunately, no option is perfectly effective all of the time. You may need to try an option for a few months and then discuss a different one if that is not working.

To Learn More

- Adolescent Medicine 206-987-2028
- Ask your child's healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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Menstrual Suppression Options

Medicine	How it is taken	Frequency	Full menstrual suppression	Advantages	Disadvantages
Progestin-only pill Norethindrone acetate (brand name Aygestin 5 mg)	Pill	Pill taken once a day at the same time each day	Up to 76% with high dose progestins at 2 years In our experience, this works well within 2 to 3 months (note: this data is from Progestin-only pills in general, not this specific one)	• Does not contain estrogen • The dose can be adjusted if you experience breakthrough bleeding	• Not approved as contraception • Breakthrough bleeding can happen if you miss doses or take them late or off schedule • Some experience hormonal side effects such as bloating and moodiness
Progestin-only pill Norethindrone (brand name Micronor 0.35 mg)	Pill	Pill taken once a day at the same time each day	Up to 76% with high dose progestins at 2 years (note: this data is from Progestin-only pills in general, not this specific one)	• Does not contain estrogen • The dose can be adjusted if you experience breakthrough bleeding	• Less effective contraception • Breakthrough bleeding can happen if you miss doses or take them late or off schedule • Some experience hormonal side effects such as bloating and moodiness
Oral combined contraceptive pills (contains estrogen and progesterone)	Pill	Pill taken once a day at the same time each day	70% at 1 year when taken continuously (skipping the last week of placebo pills that do not contain hormones)	• Provides contraception	• Breakthrough bleeding can happen if missed doses or take them late or off schedule • Small risk of blood clots • Some experience hormonal side effects such as chest tenderness, headaches, bloating and moodiness
Depo medroxyprogesterone acetate (brand name Depo Provera)	Intramuscular injection	Every 12 weeks (or as often as every 9 weeks if there is breakthrough bleeding)	50 to 60% at 1 year, 70% at 2 years	• Does not contain estrogen • Provides contraception • Less frequent dosing every 3 months	• Requires coming to clinic for injection • Some experience hormonal side effects such as bloating, weight gain, and moodiness • Prolonged use may affect bone density
Subdermal etonorgestral implant (brand name Nexplanon)	A tiny rod (smaller than a matchstick) inserted under the skin in your arm.	3 to 5 years	30%	• Does not contain estrogen • Provides very effective contraception	• Requires insertion and removal in clinic • Higher rates of breakthrough bleeding (in individuals not on testosterone)
Levonorgestrel intrauterine device (IUD) Dose varies by brand	A small device that is inserted once into the uterus	5 to 7 years	50% of people at 1 year, 60% at 5 years	• Does not contain estrogen • Provides very effective contraception	• Requires pelvic exam and intrauterine insertion in clinic • Some pain when placing the IUD • May fall out early • Initial breakthrough bleeding and cramping is common

What is breakthrough bleeding?

Breakthrough bleeding is a name for light menstrual bleeding or spotting. It can happen when you are taking medications for menstrual suppression.

Starting a medicine for menstrual suppression can cause breakthrough bleeding. Breakthrough bleeding is usually not a safety concern.

What causes breakthrough bleeding and what can I do?

Starting a new hormonal medication

Breakthrough bleeding is very common in the first 2 to 3 months of starting a new kind of menstrual suppression medicine or birth control.

If you are having breakthrough bleeding that is causing distress for more than 2 weeks after starting a new medicine or have any concerns for more serious breakthrough bleeding, please contact us via Mychart or phone to discuss whether a different dose or a different type of medicine would be better.

Other medicines

Some medicines can interfere with the effectiveness of your menstrual suppression medication. If you are starting or changing other medicines, please call us. We may need to change the menstrual suppression medicine you are taking.

Missing 1 or more pills

For information on what to do, read our handout “What If I Miss a Pill?”

seattlechildrens.org/pdf/PE1466.pdf

Taking your pill at different times

Try taking your pill at the exact same time every day. Some people set alarms on their cell phone or computers, use an iPhone app, or put the pills next to something they use every day like a toothbrush to help them remember.

Infection

Breakthrough bleeding can be associated with vaginal and cervical infections. If you do not know a likely cause of your bleeding (like missing a pill), you may want to make an appointment with us to see if there may be an infection.

What if I still have breakthrough bleeding?

Progestin-only pill

If you are on a progestin-only pill (such as norethindrone, Aygestin, or Micronor), it is usually started at a dose of 1 pill once a day. If you are still having bleeding after 2 weeks of taking the pill regularly, you can increase the dose to 2 pills once a day.

Please contact us via MyChart or phone so we can check in about how much bleeding you are having. Let us know if the bleeding is persistent and you need to increase the dose to 2 pills, so we make sure we update your prescription at your pharmacy if needed.

If you increase the dose to 2 pills, we may recommend trying a lower dose again at a later time.

Depo Provera injections

If you are using Depo Provera injections, they are usually given every 12 weeks. The injections can be given as early as every 9 weeks if needed for breakthrough bleeding.

If you begin to have bleeding more than 9 weeks after your last injection, call us to see if you can get your next injection sooner. A progestin-only pill (such as Aygestin) can sometimes be added if menstrual bleeding is happening in the first 9 weeks after the injection.

Nexplanon or IUD

If you are using Nexplanon or an IUD, a progestin-only pill (such as Aygestin) can sometimes be added.

When do I need to call the doctor?

If you have any of the following issues that can lead to large loss of blood:

- Heavy breakthrough bleeding (saturating a large product within 2 hours)
- Menstrual bleeding that previously required a trip to the emergency room
- A blood transfusion within the last 3 months
- A bleeding disorder like hemophilia or thalassemia
- Fainting, shortness of breath, and chest pain which can be signs of more serious bleeding

Call us Monday through Friday, 8 a.m. to 4:30 p.m. at 206-987-2028.

If it is after-hours, a weekend, or a holiday: call your primary care provider, go to Urgent Care, or the Emergency Room.

7/22
PE3715

Puberty Blockers

What are puberty blockers?

Puberty blockers are medicines that block puberty-related hormones that make your body go through puberty. Starting puberty blockers is a decision that is different for everyone. To make the most informed decision, this handout is meant to help you understand:

- What is puberty?
- What do puberty blockers do?
- What are the changes that will happen to my body?
- What are the benefits, risks and costs involved?

We will work with you to support the decision that is best for you. You can view a video about puberty blockers at seattlechildrens.org/gender.

How does puberty begin?

Puberty is the process the body goes through to become capable of making a baby (reproduction), as well as reach adult size and brain development. Puberty starts when your brain tells your pituitary gland to start releasing puberty-related hormones. This happens at different ages for different people.

During this time, your body starts to increase the amount of certain puberty-related hormones (Luteinizing Hormone (LH) and Follicle-Stimulating Hormone (FSH). This causes your testicles to start producing testosterone or your ovaries start producing estrogen. These hormones do not cause acne, pubic or armpit hair - those are caused by other hormones.

Body changes in people with testicles (without puberty blockers)

- Testicle growth (this improves the body's ability to make testosterone)
- Penis growth
- Pubic hair
- Increased acne, increased armpit and facial hair
- Rapid growth (growth spurt)
- Voice changes (deepens)

Body changes in people with ovaries (without puberty blockers)

- Breast changes
- Changes in body shape, including fuller hips
- Menstrual periods start (usually more than 2 years after breast changes begin)

To Learn More

- Adolescent Medicine 206-987-2028
- Ask your child's healthcare provider
- seattlechildrens.org/gender

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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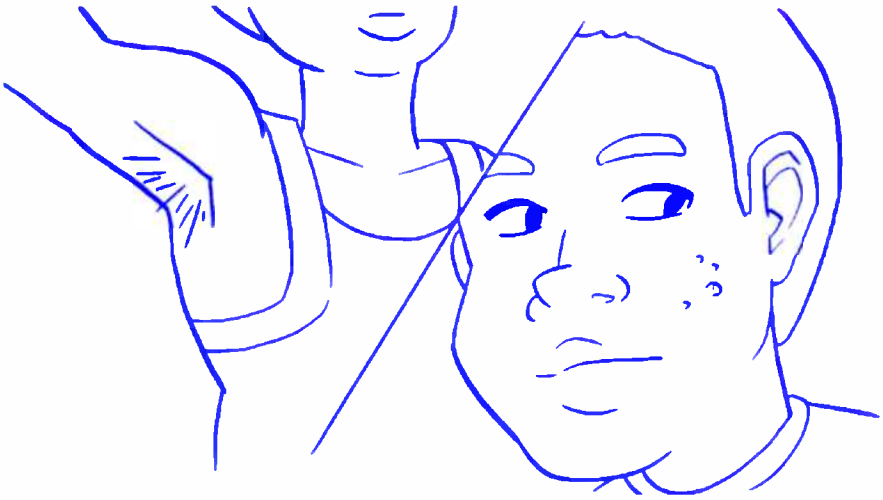
How do puberty blockers work?

Puberty blockers (called GnRH analogues) cause your body to stop releasing puberty hormones (LH and FSH). This is like hitting a 'pause button' on puberty.

Will puberty blockers stop all changes in my body?

No, puberty blockers will not stop pubic or armpit hair from growing or improve acne. Puberty blockers only make a difference for the puberty changes that make you look female or male. For example, in bodies with ovaries, breast size may get smaller if they have already started to develop. In bodies with testicles, testicle size may decrease, and penis growth will be halted.



What will happen if I start puberty blockers late in puberty?

If puberty blockers are started late in puberty, they are not able to reverse most changes that have already happened. However, puberty blockers can stop any further puberty changes.

Are puberty blockers permanent?

No, puberty blockers are not permanent. If you decide to stop puberty blockers without starting cross sex hormones, your body will start going through the puberty of your sex at birth. You can stop the puberty blockers at any time, but we will work with you on how to do that.

How long will it take them to start working?

It can take 1 to 2 months for puberty blockers to start working. Everyone is a little different. It is hard to know exactly how quickly your body will respond. In the beginning, your body may actually show more signs of puberty, but this will lessen as you continue to take the blockers.

What are the different kinds of puberty blocking medicines?

Depo Lupron or Leuprolide

This medicine is given as an injection (shot) once every 3 months. If you use this kind of puberty blocker, you will need to come to clinic every 3 months for the injection.

Histrelin

This medicine is a little plastic rod that is placed under the skin (implant) in the upper arm. The implant works for a little more than 1 year, and sometimes up to 2 years or longer. After it stops working, it needs to be removed and replaced. This can be done in the clinic or in the operating room.

Are these medicines safety approved?

We can safely and legally recommend puberty blockers for you based on our medical experience and judgement and your specific health needs. The Endocrine Society and the World Professional Association for Transgender Health support puberty blockers. The Food and Drug Administration (FDA) approves puberty blockers for children who start puberty at a very young age, but has not approved puberty blockers for transgender children.

Will I have pain?

We partner with you to prevent and relieve any pain from taking these medicines as completely as possible. No matter what the level of your pain, we join you to assess and respond right away.

If you have pain from an injection or an implant, you can take Tylenol (acetaminophen) or Advil (ibuprofen) to help relieve the pain. Use these medicines only if recommended by your healthcare provider. Check with the healthcare provider first before taking any type of medicine. Contact your Gender Clinic doctor if the pain from the injection or implant gets worse the next day or you have a rash.

Will the Depo Lupron or Leuprolide injection hurt?

The injection is given in your arm, leg or bottom. The area where you get it may be sore for about 1 day after the injection.

Numbing cream (topical lidocaine) reduces pain from injections by numbing the skin before the needle stick. Ask us if you are interested in using numbing cream before your injection.

Will the Histrelin implant hurt?

If you get the implant inserted in clinic, we will give you an injection to numb your upper arm before the procedure. If you have it done in the operating room, we will give you medicine to make you sleep (anesthesia) during the procedure.

After the procedure, your arm may be sore for about 2 days where it was inserted.

What are the risks of puberty blockers?

The long-term safety of puberty-blocking medicines is not completely understood. There may be long-term risks that we do not know about yet.

Bone health

Blocking puberty can make your bones weaker (lower bone density). This may get better when you stop the puberty blockers or start cross-hormone therapy. While on puberty blockers, we recommend taking calcium, vitamin D and doing bone strength-building exercises like walking, jumping and weight lifting. We may check your bone health every 2 years while on blockers.

Fertility

Taking puberty blockers should not affect your ability to have a baby in the future (fertility).

However, permanent damage to fertility is a concern for people who stay on puberty blockers and then take cross-sex hormones. We recommend talking about this with us to understand the potential impact on your fertility before starting any medicines.

How much does it cost?

Puberty blocker medicines can be very expensive and the cost can change every year. Some insurance companies cover them. How much your insurance covers depends on your insurance plan and requires authorization from your plan. Sometimes insurance companies will only help pay for Depo Lupron (the injection) and not Histrelin (the implant).

If you have medicine to sleep (anesthesia) to get the Histrelin implant, the costs are higher. If you have questions about coverage, you can call your insurance company. Questions you may want to ask include:

- Are these medicines covered by my insurance plan?
- What is my deductible, copay and coinsurance?
- Have I met my deductible this year?

For help navigating the insurance process, contact:

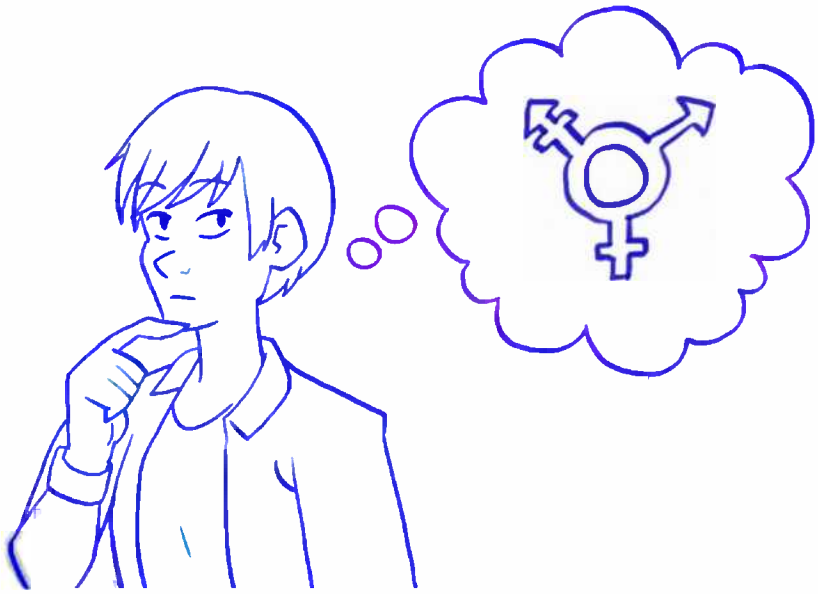
- Gender Clinic Care Navigator at 206-987-8319
- Seattle Children's Family Accounts Specialist at 206-987-5770

Are puberty blockers right for me ?

We will work hard to answer all of your questions about the benefits and risks of puberty blockers. We want you to have a good understanding of what to expect before you decide to start.

Starting puberty blockers can give you time before making more permanent gender decisions, like the starting cross-sex hormones. Puberty blockers prevent some of the male or female specific changes to the body that puberty causes. It can be distressing for transgender people to go through puberty. Puberty blockers can help with this distress by pushing the "pause button" on your puberty, which prevents puberty changes that do not match with your gender identity.

For some people, puberty blockers may reduce the need for future surgeries or other treatments. For example, breast removal (mastectomies) for transgender men, or hair removal and breast surgery for transgender women.



What about mental health therapy ?

In most cases, we ask that you and your family connect with a mental health therapist experienced in gender identity before and during treatment in the Gender Clinic. A mental health therapist can help you through decisions and changes that happen as you get older, and help your family learn how to support you through those changes.

Mental health therapists can also provide letters that are sometimes requested by doctors or insurance companies for gender-related care. Each person has a different situation. Please ask us about resources that may be right for you and your family.

When should I start taking puberty blockers?

You begin puberty blockers after your body shows signs of puberty. Usually this is after bodies with testicles have started to have increased testicle size and growth of the penis, and bodies with ovaries have started to have breast changes (breast buds). It is not safe to start puberty blockers before puberty.

How will my doctor know puberty has started?

Before starting puberty blockers, we might recommend some testing to confirm that puberty has started. These include a physical exam and a blood test called a Leuprolide Stimulation test. This type of blood test checks your hormone levels before and 1 hour after getting a Leuprolide injection. If the test shows that your hormone levels are higher after the injection, it confirms that puberty has begun.

How long can I stay on puberty blockers?

Puberty blockers are used until you decide you want to either resume the puberty process, or until you are ready to start cross-sex hormones. Because puberty blockers can make your bones weaker over time, it is best to stop taking them after about 4 years.

12/19
PE2572

GENDER-AFFIRMING HORMONE THERAPY: A TIMELINE

As part of the process of transition, some patients may seek gender-affirming hormone therapy. To help you understand the effects, we want to share this information with you. Everybody is different. The rate and extent of your changes take place depend on many factors, including your genetics, the age at which you start taking hormones, and your overall state of health.

Here is a timeline of changes promoted by the use of testosterone.

EFFECT	EXPECTED ONSET	EXPECTED MAXIMUM EFFECT	*REVERSIBLE* or PERMANENT
▶ Increased body hair and facial hair growth	1-6 months	1-2 years	Permanent
▶ Deepened Voice	3-12 months	1-2 years	Permanent
▶ Clitoral Enlargement (by 1-3 cm)	3-6 months	1-2 years	Permanent
▶ Male Pattern Baldness *(hair loss at temples and crown of head; highly dependent on age and inheritance)*	+12 months	Variable	Permanent
▶ Increased Muscle Mass and Strength *(dependent on amount of exercise)*	6-12 months	2-5 years	*Reversible*
▶ Cessation of Menstrual Periods	2-6 months	N/A	*Reversible*
▶ Body Fat Redistribution *(decreased on buttocks/hips/thighs; increased in abdomen)*	3-6 months	2-5 years	*Reversible*
▶ Skin Oiliness/Acne *(may be severe)*	1-6 months	1-2 years	*Reversible*
▶ Vaginal Atrophy *(drying)*	3-6 months	1-2 years	*Reversible*
▶ Increased Libido *(sex drive)*	Variable	Variable	*Reversible*

Here is a timeline of changes promoted by the use of estrogen.

EFFECT	EXPECTED ONSET	EXPECTED MAXIMUM EFFECT	*REVERSIBLE* or PERMANENT
▶ Breast Growth	3-6 months	2-3 years	Permanent
▶ Decreased Sperm Production/Maturation, Reduced Fertility	Variable	Variable	Possibly Permanent
▶ Decreased Testicular Volume/Size by 25-50 percent	3-6 months	2-3 years	Probably Permanent
▶ Thinning/Slowed Growth of Body and Facial Hair	6-12 months	+3 years	*Reversible*
▶ Softening of Skin/Decreased Oiliness	3-6 months	Unknown	*Reversible*
▶ Body Fat Redistribution to more Feminine Pattern	3-6 months	2-5 years	*Reversible*
▶ Decreased Muscle Mass and Strength	3-6 months	1-2 years	*Reversible*
▶ Decreased Libido *(sex drive)*	1-3 months	1-2 years	*Reversible*
▶ Decreased Spontaneous and/or Morning Erections	1-3 months	3-6 months	*Reversible*
▶ Male Sexual Dysfunction *(ex., erections not as firm)*	Variable	Variable	*Reversible*
▶ Cessation of Male Pattern Balding *(no regrowth, but loss stops)*	1-3 months	1-2 years	*Reversible*

Cox Exhibit 15 5/31/23

SO YOU WANT TO KNOW MORE ABOUT ESTROGEN...

Basic Overview

Hormone therapy for trans women is meant to feminize patients by changing fat distribution, inducing breast formation, and reducing male pattern hair growth. Estrogen is the mainstay therapy for trans female patients but there are other options that may or may not be the right choice for you. Hormone therapy is a long-term treatment that can help the patient to be happier with their body as it will be more congruent with their gender identity. Hormone therapy is not a wonder drug that will solve all problems in a patient's life but can be a step in the right direction. Guidelines do exist to help medical providers to determine when hormone therapy is appropriate for treatment and how the treatment should take place.

Things to think about

- Psychotherapy – As with any transition in life and knowing that psychotherapy is not for everyone, most people would benefit from supportive psychotherapy with a qualified psychotherapist. The therapist can help you explore new thoughts and feelings and get to know your new body and self.
- Do your research on any and all treatments that are suggested by your doctors but also understand that everyone is different. Your response or development may be very different from friends or those you see in the community and online.
- Be patient – Transitions and medications take time to see the full results. This can take 2-3 years to see the results of the medications and therapies before getting discouraged. You should also wait at least this long before seeking further invasive procedures for facial feminization. Higher doses will not bring changes faster and could endanger your general health.
- Continual care- monitoring by a doctor must be done on a routine basis to ensure that hormone levels remain at correct levels to achieve desired results.

Types of hormones

Hormone therapy for trans women can include three kinds of medications; estrogen, testosterone blockers and progesterone. Estrogen is the most common therapy but alone is often not enough to achieve desirable androgen suppression, and additional anti-androgenic therapy is also usually necessary.

Estrogen is the most common hormone and is responsible for most female characteristics. Estrogen can be given in pill, injection, creams, gel, spray or a patch. Contrary to what many have heard or believe a small dose of estrogen can achieve maximum effect for you. Higher doses do not necessarily make changes happen quicker but can endanger your general health.

- Pills are convenient, cheap and effective but less safe for those that are over 35 or smoke.
- Patches are effective and safe but can cause skin irritation as they must be worn at all times.
- Injections can cause more fluctuation in estrogen levels. These fluctuations can cause mood swings, weight gain, migraines, anxiety and possible hot flashes.

Testosterone Blockers come in two different categories. The first blocks the actions that testosterone in your body and the second prevents the production of testosterone in your body. Both are safe but do have side effects:

- Spironolactone is the most commonly used blockers and can cause excessive urination, lightheadedness and dizziness especially when first taking it. Drink plenty of fluids on this medication. This medication can have serious side effects for those with kidney problems and on some blood pressure medications. It can also cause an increase in potassium production and levels should be checked periodically.
- Finasteride and Dutasteride block the production of dihydro-testosterone which affects skin, hair and prostate. These medications are a weaker blocker than Spironolactone but also have fewer side effects. Common side effects for these drugs include impotence, loss of sex drive, dizziness, tenderness in breast.

Progesterone is a major sex hormone in women. Progesterone is typically involved in menstrual cycles and pregnancy. In trans women there is a little scientific evidence to support claims of better breast development, improved energy and better mood and sex drive. There are some studies that suggest that there is an increased risk of developing blood clots, strokes and cancer. There may be a decrease in the chance of prostate cancer but an increase in the risk of breast cancer associated with taking progresterone. You should follow all medical guidelines for someone your age in screenings for both diseases.

Medication Types

Oral	Estradiol
Parental	Estradiol valerate
(subcutaneous/intramuscular)	
Transdermal	Estradiol
Anti-androgens	Progesterone
	Medroxyprogesterone acetate
	GnRH agonist (leuprolide)
	Histrelin implant
	Spironolactone
	Finasteride

The most serious risks when taking estrogens are:

- Thrombosis
  - Deep vein thrombosis (DVT)
  - Stroke
  - Pulmonary embolism (block in a blood vessel in the lungs)
- Altered liver function.

Tips for administration of the medications

- Injections.
  - Always clean the area with alcohol before injecting and allow the alcohol to dry completely.
  - The directions will tell you to inject at a 90-degree angle to the muscle in your thigh. Before injecting pull the skin tightly in one direction and then releasing immediately after pulling the needle out will help to ensure no medication leaks out of the injection side.
  - Do not ever reuse your needles due to the risk of infection.
  - Always dispose of your needles in a safely.
  - Pull a little air into the syringe before getting the medication and push the air into the open space in the medication bottle. Then flip the medication over and line up the syringe to dose the prescribed amount.
  - Look for air bubbles in the syringe. Flick the side of the syringe to get these bubbles to rise to the top. Make sure you get all the air bubbles out of the syringe to ensure no complication.

- Patch
  - you will apply onto your back, stomach, upper arms, or thighs nightly for 24 hours.
  - At the end of that 24 hours, you will need remove the used patch and put on a new one.
  - The patch site should be rotated, with an interval of 7 days between applications to the same site.

- Storage
  - Keep out of the reach of children.
  - Do not keep outdated medicine or medicine you no longer need.
    - Ask your healthcare professional how you should dispose of any medicine you do not use.
  - Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.
  - Keep the medicine in a safe place. Do not give it to anyone else, even if you have the same symptoms.

What to expect

Consider the effects of hormone therapy as a second puberty, and puberty normally takes years for the full effects to be seen. Taking higher doses of hormones will not necessarily bring about faster changes, but it could endanger your health. And because everyone is different, your medicines or dosages may vary widely from those of your friends, or what you may have read in books or online.

3 areas to expect changes

- ***Physical***
  - Skin will be one of the first changes you notice in that it will become drier, thinner, pores will shrink and there will be less oil production.
  - You may notice things "feel different" when you touch them and the way you perceive pain and temperature may change.

- Within a few weeks you may develop small buds under your nipples which may be slightly painful to the touch. They may be uneven from right and left. This is normal and the pain will decrease of the next few months.
  - It is important to note that breast development will vary from woman to woman. Many trans women only develop to an A cup or a small B cup.
  - High doses of estrogen can cause abnormal breast development so sticking to your doctor's prescription is necessary.
- Body fat redistribution will start with your hips and thighs. The muscles in your arms and legs will become less defined and as the fat below the surface thickens it will become much smoother. Your eyes and face will also develop a thicker fat layer which will feminize your features but this process can take 2-3 years to fully develop. Your muscle mass and strengths will decrease significantly. Exercise should be a part of your routine for both general health but also to decrease the likelihood of weight gain during this process.
- The body hair that you have will decrease in thickness and growth rate. It may not go away altogether, which is normal for all women. Facial hair will act the same way and may not go away all together. If you have a scalp that is balding, hormone therapy may stop it or slow it but likely will not regrow hair.

- ***Emotional***
  - Emotional changes vary from person to person. Hormone therapy is similar to going through puberty and for many puberty can be a roller-coaster of emotions. You may find that some of your interests, tastes or pastimes may change. You may also notice that you have a wider range of emotions or feelings or that your relationships with people change.

- ***Reproductive System***
  - You should assume that within a few months of starting hormone therapy you will become permanently sterile. Some people do retain a sperm count during hormone therapy but that is not the norm.
    - If you wish to have biological children in the future or are unsure you will need to preserve your sperm in a sperm bank prior to starting hormone therapy.
    - If you are sexually active with a woman who is able to become pregnant, you should always use birth control.
  - Your testicles will shrink in size likely to less than half their original size.

What Not to expect

- Hormones will not be able to change the tone and pitch of your voice. During puberty, the larynx or voice box grows thicker and larger which deepens the voice. Hormone therapy will not reverse thickening of vocal cords that happened during puberty. Changes in voice can be attainted through voice therapy which is a non-surgical intervention with a speech therapist or pathologist.
- Change shape, size, structure of bones will not change based on estrogen. There will be a change over time in the look of the face due to a redistribution of fat so you should wait at least 2-3 before undertaking any facial feminization surgeries to give the hormones time to work fully

- Reduce or eliminate Adam's apple which can only be done through a Chondrolaryngoplasty (commonly called tracheal shave). A tracheal shave will not change or alter the voice in any way.
- As stated about estrogen will help hair to decrease in thickness and growth rate over the body but it will not eliminate all terminal hair follicles that are associated with masculine hair growth patterns. Chest, back, facial hair may need additional interventions such as laser hair removal to achieve your desired effect.

Do I need to be monitored?

Being under proper medical supervision will ensure that your body is absorbing the medication properly. This will also help your doctor to ensure to identify any health issues early and allow for your hormone therapy to be adjusted to compensate or to change any other medications. It is also important to give your doctor your entire family medical history and any additional medications you may be taking to ensure there is no negative interactions.

What if I take hormones bought without a prescription?

It can be very tempting to purchase without a prescription from a doctor. While making this choice may be understandable it is unwise due to the risks to your general health. The hormones and doses that you read about on the internet or that are prescribed for a friend will likely not be the correct dosing for you as each individual is different.

The main risks and dangers of self-medicating:

- The products may not be authentic and may therefore have no effect at all, so you may be wasting your money.
- The products may be of poor quality and may even be harmful to your general health. There is not way for you to be sure that the oil
- You may not have a full understanding the possible risks and side effects for the doses and hormones you are taking.
- You may not have a full understanding of the consequences of combining hormones with any other medication or herbal or supplement products that you might be taking
- You will not have had a full medical work up to ensure you have no other conditions that will be affected by the hormones you are taking
- The dose and the manner you are taking the medication (pills vs patches) may not be appropriate for you

SO YOU WANT TO KNOW MORE ABOUT "T"...

Testosterone Basic Overview

Hormone therapy for trans men is meant to suppress female secondary sex characteristics such as menstruation, fat redistribution and to masculinize. Testosterone can show effects within the first few months of treatment and patients will continue to see changes for the next few years. Hormone therapy is a long-term treatment that will help the patient to be happier with their body as it will be more congruent with their gender identity. Hormone therapy is not a wonder drug that will solve all problems in a patient's life but can be a step in the right direction. Guidelines do exist to help medical providers to determine when hormone therapy is appropriate for treatment and how the treatment should take place.

Things to think about

- Psychotherapy – As with any transition in life and knowing that psychotherapy is not for everyone, most people would benefit from supportive psychotherapy with a qualified psychotherapist. The therapist can help you explore new thoughts and feelings and get to know your new body and self.
- Do your research on any and all treatments that are suggested by your doctors but also understand that everyone is different. Your response or development may be very different from friends or those you see in the community and online.
- Be patient – Transitions and medications take time to see the full results. This can take 2-3 years to see the results of the medications and therapies before getting discouraged. You should also wait at least this long before seeking further invasive procedures. Higher doses will not bring changes faster and could endanger your general health.
- Continual care- monitoring by a doctor must be done on a routine basis to ensure that hormone levels remain at correct levels to achieve desired results.

Types of hormones

Testosterone comes in several forms with most transgender men use an injectable form at the beginning. Some patients start slowly and increase the dose over time while others begin at the typical dose levels. Both approaches have their pros and cons and remember that treatment will be different from patient to patient and you should discuss any and all concerns you have with your doctor. Regardless of your approach it is important to remember that more testosterone will not increase the changes or speed them up. Too much testosterone can be converted to estrogen which can lead to increased risk of uterine imbalance and cancer. It can also make you feel more anxious and agitated.

Medication Types

Oral	Testosterone undecanoate
(not available in United States)	
Parental	Testosterone enanthate, cypionate
(subcutaneous, intramuscular)	
Implant	Testopel®
(subcutaneous)	
Transdermal	Testosterone gel (1%)
	Testosterone patch

The most serious risk when taking testosterone is polycythaemia (over-production of red blood cells).

Tips for administration of the medications

- ***Gel***
  - Make sure that you wash your hands with soap and water before and after applying the gel.
    - The gel can be transferred to another person if they touch or rub the skin where it has been applied. Make sure to wash your hands after applying gel.
  - Apply gel to a clean, dry, intact skin where your doctor has prescribed it to go. Applying it to other places (i.e. face) will not assist in quicker results.
  - Allow the gel to dry on your skin before you cover it with clothing.
  - Wait for at least 2 – 5 hours after applying this medicine before showering or swimming.

- ***Injections***
  - Note: testosterone is a thick medication and can be difficult to work with at first.
  - Always clean the area with alcohol before injecting and allow the alcohol to dry completely.
  - The directions will tell you to inject at a 90-degree angle to the muscle in your thigh. Before injecting pull the skin tightly in one direction and then releasing immediately after pulling the needle out will help to ensure no Testosterone leaks out of the injection side.
  - Do not ever reuse your needles due to the risk of infection.
  - Always dispose of your needles in a safely.
  - Pull a little air into the syringe before getting the medication and push the air into the open space in the medication bottle. Then flip the medication over and line up the syringe to dose the prescribed amount.
  - Look for air bubbles in the syringe. Flick the side of the syringe to get these bubbles to rise to the top. Make sure you get all the air bubbles out of the syringe to ensure no complication.

- ***Patch***
  - You will apply onto your back, stomach, upper arms, or thighs nightly for 24 hours.
  - At the end of that 24 hours, you will need remove the used patch and put on a new one.
  - The patch site should be rotated, with an interval of 7 days between applications to the same site.

- ***Storage***
  - Keep out of the reach of children.
  - Do not keep outdated medicine or medicine you no longer need.
    - Ask your healthcare professional how you should dispose of any medicine you do not use.
  - Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.
  - Keep the medicine in a safe place. Do not give it to anyone else, even if you have the same symptoms.

What to expect

Consider the effects of hormone therapy as a second puberty, and puberty normally takes years for the full effects to be seen. Taking higher doses of hormones will not necessarily bring about faster changes, but it could endanger your health. And because everyone is different, your medicines or dosages may vary widely from those of your friends, or what you may have read in books or online.

3 areas to expect changes

- ***Physical***
  - Skin will be one of the first changes you notice in that will become thicker and oily. Pores will get larger. You may develop acne, which can be severe. Skin care practices and cleansing will be important during this time. You may also notice your body odor and urine will change and you may sweat more.
  - You may notice things "feel different" when you touch them and the way you perceive pain and temperature may change.
  - Your eyes and face will also develop a thinner fat layer and become more angular which will masculinize your features but this process can take 2-3 years to fully develop.
  - You will not see a major change in your breasts other than a possible slight decrease. There may be some breast pain.
  - Body fat redistribution will start with your hips and thighs becoming smaller. Arms will start to have more muscle definition. You may also notice an increase in fat around your abdomen.
  - Your muscle mass and strengths will increase. Exercise should be a part of your routine for both general health but also to decrease the likelihood of weight gain during this process, especially around the abdomen.
  - Many trans men notice some degree of balding, especially in the front temples. Depending on genetics and age you may experience male pattern baldness to some degree.
  - The body hair that you have will increase in thickness and growth rate. This can be a slow process and take up to 5 years to see final results. You will likely see a hair pattern similar to those of men in your family.

- Facial hair varies from person to person as it does with non-trans men. Some men will grow full beards quickly while others can take years to full grow one and others will be unable to do so. This change depends on genetics and what age you start your testosterone therapy.

- ***Emotional***
  - Emotional changes vary from person to person. Hormone therapy is similar to going through puberty and for many, puberty can be a roller-coaster of emotions. You may find that some of your interests, tastes or pastimes may change. You may also notice that you have a change in the range of emotions or feelings or that your relationships with people change.

- ***Reproductive System***
  - You may notice a change in your periods at first which can vary from person to person on being lighter and for a shorter time to being thicker and longer lasting before they stop.
  - Testosterone will lower your ability, but will not eliminate, your changes of getting pregnant. You should always use a method of birth control to prevent pregnancy. If you do think you are pregnant you will not to stop testosterone as it can endanger the fetus.
  - You may notice soon after starting treatment you will likely notice a change in your libido. You will also notice that your clitoris will begin to grow and will be larger when aroused. You will also find different sex acts and parts of your body will bring you pleasure. Your orgasms will also feel different, less than a full body experience. Some people do find that their sexual orientation changes on testosterone and those feeling should be explored. Psychotherapy will assist with dealing with these changing feelings and let you explore them in a safe environment.

What Not to expect

- Testosterone will not get rid of breast tissue. While there will be a redistrubiton of fat, there will not be a way to get rid of the breast tissue or make you have a flat or masculine chest.
- Testosterone will not make you taller. Do not expect a growth spurt from starting hormones as your growth plates have likely fused.
- Muscles will not appear with no work for it. Testosterone may make it easier for you to gain muscle mass but you will likely need to add or increase strength training to your routine to gain significant muscle mass.

Do I need to be monitored?

Being under proper medical supervision will ensure that your body is absorbing the medication properly. This will also help your doctor to ensure to identify any health issues early and allow for your hormone therapy to be adjusted to compensate or to change any other medications. It is also important to give your doctor your entire family medical history and any additional medications you may be taking to ensure there is no negative interactions.

What if I take hormones bought without a prescription?

It can be very tempting to purchase hormones without a prescription from a doctor. While making this choice may be understandable it is unwise due to the risks to your general health. The hormones and doses that you read about on the internet or that are prescribed for a friend will likely not be the correct dosing for you as each individual is different.

The main risks and dangers of self-medicating:

- The products may not be authentic and may therefore have no effect at all, so you may be wasting your money.
- The products may be of poor quality and may even be harmful to your general health.
- You may not have a full understanding the possible risks and side effects for the doses and hormones you are taking.
- You may not have a full understanding of the consequences of combining hormones with any other medication or herbal or supplement products that you might be taking
- You will not have had a full medical work up to ensure you have no other conditions that will be affected by the hormones you are taking
- The dose and the manner you are taking the medication (pills vs patches) may not be appropriate for you

Is Gender Affirming Care Safe & Effective

- Gender Affirming care is safe, effective, and important to the health and well-being of transgender people. This life-saving care encompasses both social affirmation (e.g., supporting a transgender person's chosen name, dress etc.) and medical affirmation, which allows transgender people to live in a body that matches the gender with which they identify.
- Expert medical standards of care on the provision of gender-affirming care have been continuously maintained and updated for more than 40 years. These standards require providers to carefully evaluate each patient and make decisions in the patient's best interest.
- Every major U.S medical and mental health organization, including the American Medical Association, American Academy of Pediatrics, Federation of Pediatric Organizations, and American Psychological Association, supports access to gender affirming support and care for transgender young people and adults.
- Researchers and health experts have studied the effects of gender-affirming care for decades. The scientific evidence shows that transgender people who have access to the care they need see a positive impact on their mental and physical health. (See further detail below.)

Standards of Care for Gender Affirming Care

- Every person has unique health needs, including transgender people. Health care providers follow well-established expert best practices to prescribe age-appropriate gender-affirming support and care.
    - For prepubertal children, the only intervention is social support, such as wearing different clothes or using a chosen name. Social support (sometimes called social transition) can help kids understand and explore their gender as they grow up and is endorsed by the American Academy of Pediatrics, which is the national expert medical society for pediatricians. Social transition is entirely reversible.
    - For adolescents with clinically recognized gender dysphoria who have just started or are well into puberty, the first step in medical gender affirmation is typically the use of medications that temporarily pause puberty, otherwise known as puberty blockers. These medications have been used to treat both transgender and non-transgender young people experiencing puberty at the wrong time for more than 30 years and have been shown to be safe and effective.[i]
    - Puberty delay medications can be stopped at any time, and puberty starts back up after being temporarily paused.
    - If an adolescent continues to experience gender dysphoria, gender-affirming hormones are often used to help bring the person's body into alignment with their gender. Gender-affirming hormone therapy has been safely and effectively used for both transgender and non-transgender people.

- It is recommended that genital surgeries (commonly referred to as "top" or "bottom" surgeries) should not be carried out until (i) patients reaches the legal age of majority, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity.[ii]

- Mental health professionals are an integral part of gender affirmation for transgender youth to make sure that young people and their families feel safe and supported.

Substantial Scientific Evidence Supports Access to Gender-Affirming Care

- Recent research found that 98% of transgender youth who begin gender affirming medical treatment in adolescence continue gender-affirming medical care into young adulthood.[iii] This adds to the vast body of scientific evidence demonstrating that gender-affirming care is essential for improving the mental health and overall well-being of transgender people.

- Other studies have found similar positive impacts[iv] on the mental health of transgender and nonbinary youth.

  - Example: A 2018 review of over 50 research studies indicated that gender-affirming health care services are associated with better mental health for transgender people, including reduced suicide attempts, less depression, and higher life satisfaction.

  - Example: A 2022 review of over 50 studies found reduced rates of suicide attempts, anxiety, depression, and symptoms of gender dysphoria along with higher levels of life satisfaction, happiness, and quality of life after gender affirming surgery among transgender adults.

  - Example: A 2022 peer-reviewed study found that receipt of gender affirming care among young people aged 13 to 20 was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12-month follow-up.

  - Example: A 2021 peer-reviewed study found that transgender and nonbinary adolescents (those that don't identify with one particular sex) with access to gender affirming hormone therapy treatments had nearly 40% lower odds of having had a suicide attempt in the past year, compared to peers who did not have access to affirming care.

  - Example: A 2022 review of 16 studies on gender affirming care for transgender youth found that this care results in favorable mental health outcomes.

  - Example: A 2016 peer-reviewed study showed that transgender youth who were socially supported in their gender identity had much better mental health than those who were not supported in their identity.

Gender Affirming Care Services at Riley Hospital for Children

- At Riley, all gender affirming Care interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria. (NOTE: Gender Dysphoria is defined as the distress and unease experienced if the gender identity and sex at birth are not completely congruent.)
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- As discussed above, puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.
- Consistent with current standards of care in the U.S. , Riley does not conduct top or bottom surgeries on any patient before the age of 18. These guidelines exist to ensure that patients receive the individualized and age-appropriate care they need in consultation with their families and their doctors.

Gender Affirming Interventions for *Pediatric Patients* (less than 18yo) at Riley Hospital for Children

Services Provided	Services NOT Provided
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430465/#CIT0061

[ii] SOC V7_English.pdf (wpath.org), see page 21

[iii] Van der Loos, M. A. T. C., Hannema, S. E., Klink, D. T., den Heijer, M., & Wiepjes, C. M. (2022). Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: A cohort study in the Netherlands. The Lancet Child & Adolescent Health, 6(12), 869–875. https://doi.org/10.1016/s2352-4642(22)00254-1

[iv] Ramos, G. G. F., Mengai, A. C. S., Daltro, C. A. T., Cutrim, P. T., Zlotnik, E., & Beck, A. P. A. (2021). Systematic Review: Puberty suppression with GnRH analogues in adolescents with gender incongruity. Journal of Endocrinological Investigation, 44(6):1151-1158. doi: 10.1007/s40618-020-01449-5